SOMNO*lab* 2

SOMNO*lab* 2 effort, polygraphy system

SOMNO*lab* 2 PG, expanded polygraphy system

SOMNO*lab* 2 PSG (R&K), polysomnography system

SOMNO*lab* 2 PSG (AASM), polysomnography system

Description of device and instructions for use

WEINMANN
medical technology

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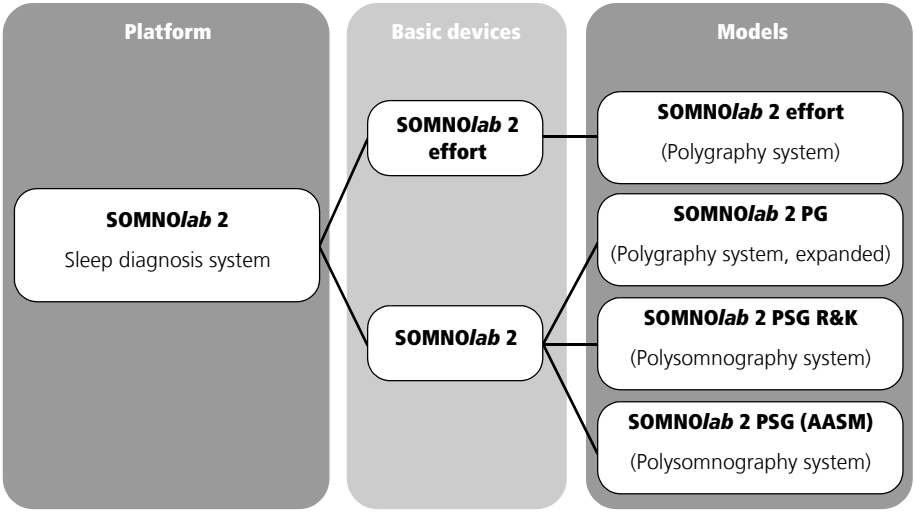
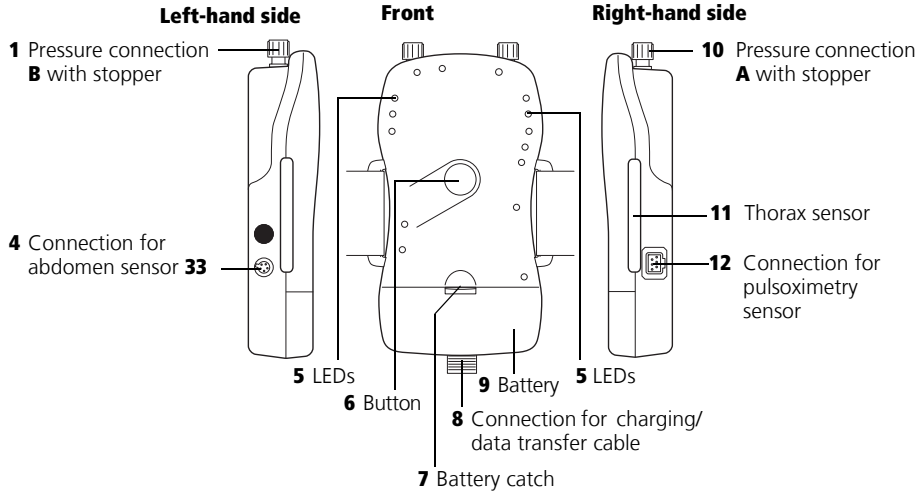
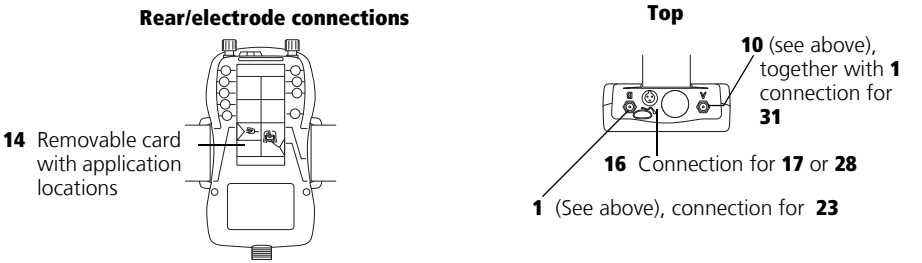
Overview

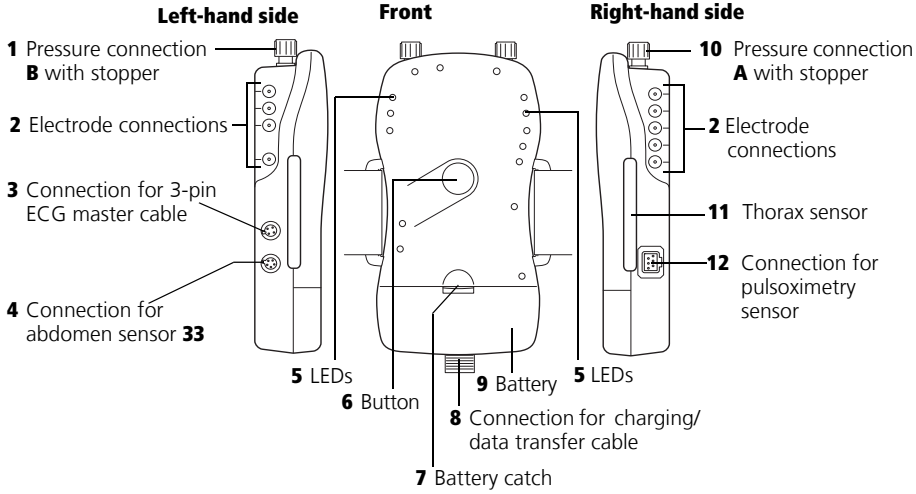

Platform
Basic devices
Models
SOMNOlab 2
Sleep diagnosis system
SOMNOlab 2 effort
SOMNOlab 2
SOMNOlab 2 effort
(Polygraphy system)
SOMNOlab 2 PG
(Polygraphy system, expanded)
SOMNOlab 2 PSG R&K
(Polysomnography system)
SOMNOlab 2 PSG (AASM)
(Polysomnography system)

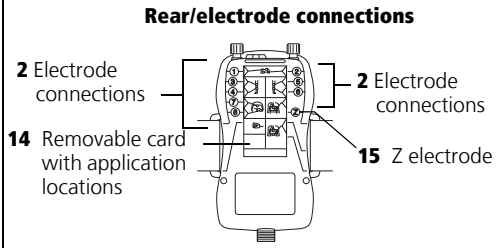
SOMNO*lab* 2 effort polygraphy device

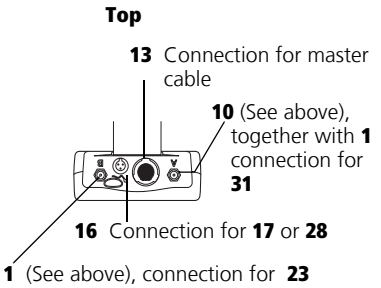



Rear/electrode connections
14 Removable card with application locations
Top
10 (see above), together with 1 connection for 31
16 Connection for 17 or 28
1 (See above), connection for 23

SOMNO*lab* 2 polygraphy device and SOMNO*lab* 2 R&K / AASM polysomnography devices

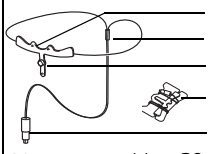




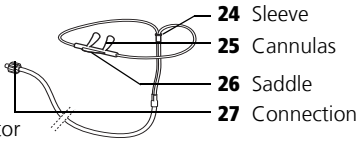

Top
13 Connection for master cable
10 (See above), together with 1 connection for 31
16 Connection for 17 or 28
1 (See above), connection for 23

Sensors

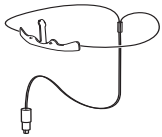
17 Respiratory flow snore sensor



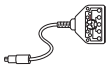
23 Respiratory flow nasal cannula



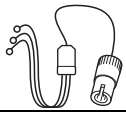
28 Respiratory flow oral sensor



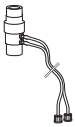
29 Master cable **(only with PSG (R&K) or PSG (AASM))**



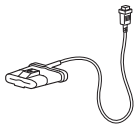
30 3-pin ECG master cable **(only with PSG (R&K) or PSG (AASM))**



31 Pneumo-T-adapter



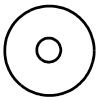
32 Pulsoximetry sensor



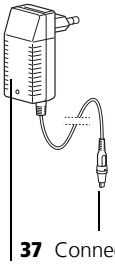
33 Abdomen sensor

PC elements

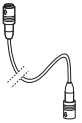
34 CD-ROM



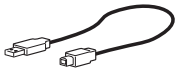
35 Power supply unit



38 Charging/data transfer cable

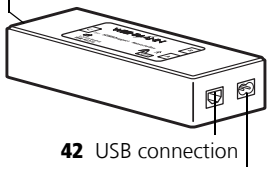


39 USB cable



40 USB/PC electrical isolation module

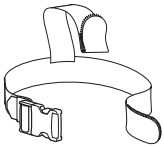
41 Connection for charging/ data transfer cable



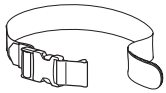
44 CompactFlash card

Belts

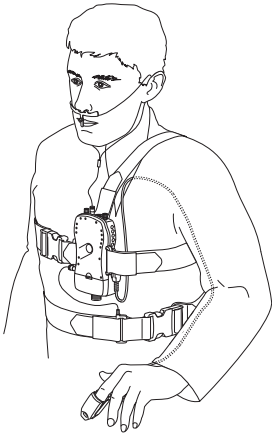
45 Attachment belt with connecting strap

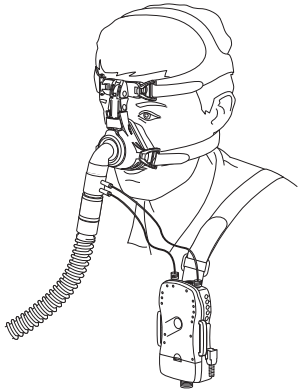


46 Abdominal belt with connecting strap



Examples of use





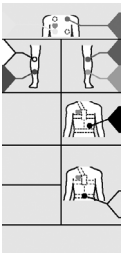
Potential markings on application parts

General markings on the application parts

Symbol	Meaning
	Date of manufacture
	Follow instructions for use
CE 0197	CE symbol (confirms that the product conforms to the applicable European directives)
	Type BF application part
	Do not dispose of the device with domestic waste

Special markings on SOMNO*lab* 2

Symbol	Meaning
IPX 0	No protection against ingress of water
SN xxxx	Serial number
1-8 Z	Free electrophysiological inputs (not on the SOMNO*lab* 2 effort)
A, B	Pressure connections
	Battery
	Label to differentiate between polysomnography devices (with PSG (R&K) or PSG (AASM)) and polygraphy devices (without options); can be affixed to the polysomnography device if required.
	Label to distinguish between the SOMNO*lab* 2 PG and SOMNO*lab* 2 effort polygraphy devices.

Symbol	Meaning
	Application locations for sensors
	HF transmitter (not on the SOMNO*lab* 2 effort)
	Follow instructions for use

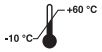
Special markings on the USB/PC electrical isolation module

Symbol	Meaning
	Electricity supply/direct current; connection for power supply unit (converter box)
A	SOMNO*lab* 2 connection (USB/PC electrical isolation module)
B	Power supply unit connection (USB/PC electrical isolation module)
C	PC connection (USB/PC electrical isolation module)

Special markings on the power supply unit

Symbol	Meaning
	Protection class II
	Input
	Output
	Only for use indoors

Special markings on the packaging

Symbol	Meaning
	Intended to be used once and then disposed of
	Humidity in operation, transport and storage
	Transport and storage temperatures
	Protect from wet
	Fragile
CE 0197	CE symbol (confirms that the product conforms to the applicable European directives)

1. Description

Note
These instructions for use describe the devices of the SOMNO*lab* 2 PG platform. Sections which are not relevant to the SOMNO*lab* 2 effort or which are relevant only for the delivery options PSG (R&K) and PSG (AASM) are marked accordingly.

The item numbers listed in the text which follows are identical to the item numbers in the overview on pages 4, 5 and 6.

1.1 Intended use

SOMNO*lab* 2/SOMNO*lab* 2 effort is a data recording system for registering, recording and storing biosignals.

It is used to identify sleep-related respiratory disorders and associated risk factors, as well as other sleep disorders (e.g. PLM), to support diagnosis and for making therapy settings and checks.

Fields of use are inpatient and outpatient examinations in sleep laboratories, and outpatient examinations in the medical field based outside hospitals. The signals recorded are transferred to the PC software wirelessly (does not apply to SOMNO*lab* 2 effort), by cable or by memory card.

The SOMNO*lab* PC software is for recording, saving, processing, visualizing, evaluating, documenting and archiving patient-related biosignals and for configuring the device.

The device is operated by the doctor instructed by the medical devices consultant and by professionals

instructed by the doctor or by a patient who has received instruction.

As an option, SOMNO*lab* 2 can be expanded into a polysomnography device (does not apply to SOMNO*lab* 2 effort).

There is no monitoring of emergency or intensive care patients. The system does not generate alarms.

SOMNO*lab* 2/SOMNO*lab* 2 effort is made up of the components below:

- basic device
- sensors
- application parts
- Li ion battery
- medically-licensed power supply unit with USB charging cable to charge the battery and to transfer the stored data to a PC via an electrically isolated USB port

1.2 Description of function

General information about the SOMNO*lab* 2

- SOMNO*lab* 2 generates information signals (e.g. status of battery charge) which are visualized in graphical form and saved by the PC system. These information signals are for checking the presence of signals for recording and for checking the function of the device. This avoids faulty recordings and the repeat night measurement which would otherwise be required.
- The system does not generate alarms.

- The automatic analyses (PLM, snoring, sleep stage, arousal and cardiorespiratory analysis) are performed offline in the PC from the signals stored and support the person making the evaluation in diagnosing sleep disorders and in introducing and checking therapy.
- With regard to electrical safety, PC systems are not part of the SOMNO*lab* 2 application part due to the application part being electrically isolated from the PC system. The PC system used must satisfy the terms of EN 60950.
- The PC software is for visualizing, evaluating, documenting and archiving long-term investigations for the diagnosis of sleep disorders on a patient-specific basis. The system is configured for this and the data transferred are analyzed automatically offline. The PC software allows the user to enter comments. The evaluator can reclassify analysis results manually.
- The system is designed for people weighing 20 kg or more, using the sensors specified by Weinmann.
- Professionals prepare the measurement, operate the SOMNO*lab* PC software and charge the battery.
- The EEG electrodes for the master cable are attached to the patient and connected to the system by professionals **(only with PSG (R&K) or PSG (AASM))**.
- Following instruction by professionals and using the instructions for use for patients, the patient is in a position to attach the remaining sensors and the device him or herself.

Options

Four models of the SOMNO*lab* 2 are available:

- SOMNO*lab* 2 effort
- SOMNO*lab* 2 PG
- SOMNO*lab* 2 PSG (R&K)
- SOMNO*lab* 2 PSG (AASM)

The scope of supply for the SOMNO*lab* 2 effort and SOMNO*lab* 2 PG polygraphy devices includes either only the SOMNO*lab* 2 effort components or all the basic components.

The scope of supply for the polysomnography devices includes all the basic components plus a master cable and the correspondingly adapted firmware (PSG (R&K) or PSG (AASM)).

SOMNO*lab* 2 effort facilitates fast, easy polygraphy. SOMNO*lab* 2 PG facilitates more detailed polygraphy.

The SOMNO*lab* 2 PSG (R&K) allows polysomnography to be performed using SOMNO*lab* 2. In the process, all the parameters for classifying sleep are recorded and this allows sleep stages to be determined in accordance with the RECHTSCHAFFEN und KALES standard. The precise positioning of the electrodes is described in the "Manual of standardized terminology, techniques and scoring systems for sleep stages of human subjects" by RECHTSCHAFFEN and KALES (1968).

Note
SOMNO*lab* 2 has been tested only with Artisana sleep stage and arousal analysis.

The SOMNO*lab* 2 PSG (AASM), likewise, allows polysomnography to be performed with SOMNO*lab* 2. This option allows sleep stages to be determined in analogy to the AASM standard of 2007. The precise positioning of the electrodes is described in "The AASM Manual for the Scoring of Sleep and Associated Events" of 2007.

If you wish to acquire one of these options retrospectively, send the device straight to:

Zentrum für Produktion, Logistik, Service
Weinmann Geräte für Medizin GmbH + Co. KG

Siebenstücken 14
D-24558 Henstedt-Ulzburg
Germany

Function of SOMNO*lab* 2/SOMNO*lab* 2 effort basic devices

The basic devices have the following intended use/ record the following sleep-related parameters:

- 4 freely-configurable electrophysiological channels (E - G1/E - G4), which can optionally be set for EMG, EOG, EEG and ECG parameters with the corresponding electrodes (does not apply to SOMNO*lab* 2 effort);
- thorax and abdomen movements;
- oxygen saturation (SpO_2; by pulsoximetry);
- pulse frequency (by pulsoximetry);
- nasal respiratory flow;
- oral and nasal respiratory flow;
- oral respiration;
- snoring;
- patient position;
- xPAP pressure;
- heart frequency (does not apply to SOMNO*lab* 2 effort);
- pulse wave;
- quality index of oxygen saturation;
- 1 ECG channel (only using the appropriate PSG (R&K) or PSG (AASM) master cable));

- 5 ExG channels (only using the appropriate PSG (R&K) or PSG (AASM) master cable)).

SOMNO*lab* 2 processes and stores all measured signals on the integrated CompactFlash card. The data are read out either via USB cable or by reading out the CompactFlash card using a card reader unit. When used in fixed mode, SOMNO*lab* 2 can transfer the recorded data online either wirelessly or by cable to the SOMNO*lab* software which also saves the data. Online transmission of data is not possible with the SOMNO*lab* 2 effort.

Existing hospital networks may be used for online monitoring with the aid of SOMNO*lab* 2. If data are lost, for example when leaving the examination room, you can supplement these data with those stored on the CompactFlash card. SOMNO*lab* 2 is supplied with power by a replaceable battery, making it independent of the electricity supply. Replacing the battery does not cause the loss of any saved data, as these are archived on the memory card. Once 30 minutes have passed without a battery or a power supply, however, the device will have to be reconfigured. You can also leave the device permanently connected to the electricity supply and operate it using the charging/data transfer cable.

SOMNO*lab* 2 has a built-in position sensor. The sensor registers if and when the patient is lying on his/her front, back or side or whether s/he is upright. The device likewise has an effort sensor integrated in the housing. Integration reduces the amount of cleaning required and increases the service life of the sensor.

Use key **6** to start a sensor test/impedance check with a double-click (nicht bei SOMNO*lab* 2 effort).

LEDs allow you to determine during a sensor test/ impedance check whether an electrode is well

attached and, if not, which one it is; the attachment of the sensors can also be checked.

In addition, SOMNO*lab* 2 shows by means of a yellow LED next to the battery symbol on the battery whether the battery is currently being charged. Charging status can also be interrogated by the SOMNO*lab* PC software, as a capacity monitoring function is integrated in the battery.

You can transfer the saved data to the PC via the USB/PC electrical isolation module. It can likewise be used to charge the battery using the power supply unit supplied. A battery can also be charged if it is not inserted in the device.

The SOMNO*lab* PC software is for recording, saving, processing and evaluating biosignals. This is to support the diagnosis process and set and check the therapy of sleep disorders. The firmware for the SOMNO*lab* 2/SOMNO*lab* 2 effort basic devices communicate with the SOMNO*lab* PC software via a secured data transmission protocol.

Function of the SOMNO*lab* PC software

The data transferred during the measurement are saved and visualized. The data read in after the measurement are automatically analyzed in accordance with time and value criteria and the occurrence of respiratory problems is registered.

The SOMNO*lab* PC software can perform the following automatic analyses as a function of the data recorded:

- PLM analysis (not on the SOMNO*lab* 2 effort)
- snore analysis
- cardiorespiratory analysis
- arousal analysis (not on the SOMNO*lab* 2 effort)

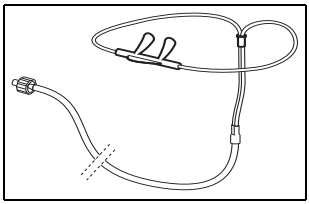
- sleep stage analysis (not on the SOMNO*lab* 2 effort)

You can assess the results in accordance with your own criteria on the basis of the analysis results and the signals displayed.

Function of the sensors

The sensors have the following intended use/record the following sleep-related parameters:

- electrodes for the electrophysiological channels;
- effort sensors (thorax and abdomen movements);
- pulsoximetry sensor for detecting oxygen saturation, pulse frequency and pulse wave;
- respiratory flow snore sensor (thermistors and microphone);
- respiratory flow nasal cannula (pressure sensor);
- oral thermistor for recording oral respiration for therapy check (thermistors);
- Pneumo-T-adapter for detecting respiratory flow, snoring and xPAP pressure (pressure sensor).



Note
See also the instructions for use enclosed with the nasal cannula.

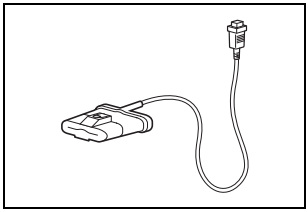
Respiratory flow nasal cannula 23

The respiratory flow nasal cannula detects respiratory flow and snoring in combination with the pressure sensor integrated in SOMNO*lab* 2. Inspiration is registered by the vacuum generated, exhalation via the overpressure generated.

Snoring generates pressure fluctuations in the nostrils which are likewise registered. Pressure measurement reacts more sensitively to slight flow limitations than thermal measurement when the mouth is closed. It is independent of ambient temperature and also allows a visual assessment of

the temporal flow contour. The signals may be attenuated in oral respiration, so we recommend simultaneous use of the respiratory flow oral sensor.

Signal display and automatic analysis are adapted to suit the original Weinmann nasal cannula.



Pulsoximetry sensor 32

The pulsoximetry sensor is used to measure pulsoximetry signals, oxygen saturation of the blood and the patient's pulse frequency.

- The primary components of the sensor are two LEDs and a receiver diode.
- Several SpO_2 values are determined for each pulse wave (split pulse wave algorithm).

  For each oxygen saturation value recorded, SOMNO*lab* 2 calculates a quality index which indicates the quality/accuracy of the SpO_2 value measured.

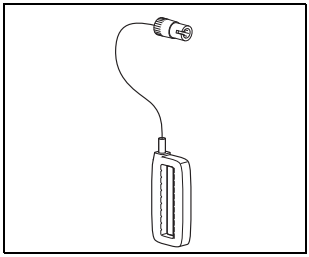
  If the signal is disrupted by movements, the number of useable measured values is reduced. Where signals are not disrupted, there is a high number of signals available. A disrupted measured signal accordingly generates a low-quality value, whilst an undisrupted measured signal results in a high-quality value.

  The quality signal adopts values of between 0 and 100 %.

  The quality signal can be helpful when assessing long-term SpO_2 measurements, as it suggests that artifacts occurred during the measurement.

Note
The changes in pulse frequency measured correspond sufficiently accurately to the changes in heart frequency triggered by a sleep-related apnea syndrome.

Note
See also the instructions for use enclosed with the pulsoximetry sensor.



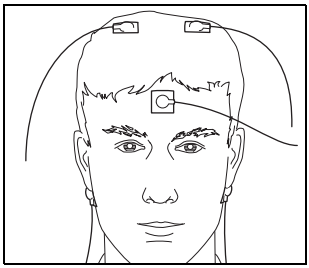
Thorax sensor 11 and abdomen sensor 33

The thorax and the abdomen sensor are for recording movements of the thorax and abdomen.

In this process, respiratory movements cause changing tensions on the measuring sensors in the attachment belts. The measuring sensors convert the movements into electrical signals as a consequence of the piezoelectric effect.

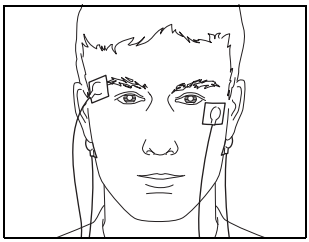
Electrophysiological signals

Electrophysiological signals are measured by electrodes. Gold cup or adhesive electrodes can be used for this.



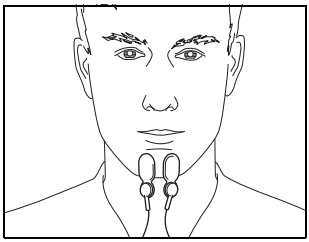
- Electroencephalogram (EEG)

  The EEG records electrical activity in the brain, so-called brain currents, by using electrodes to measure and record fluctuating voltages. In polysomnography, the EEG allows information about sleep stages to be deduced, for example.



- Electrooculogram (EOG)

  The EOG registers eye movements. Voltages generated by the movements of the eye are registered as an electric dipole in adjacent electrodes.



- Electromyogram (EMG)

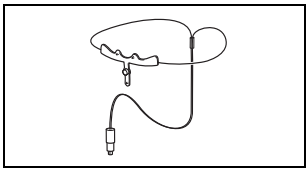
  The EMG registers muscle activity at the chin/ legs.

The EMG on the chin is required to distinguish the different stages of sleep. The EMG on the legs is specifically for diagnosing "restless legs syndrome" (RLS) and "periodic leg movement in sleep" syndrome (PLMS).

- Electrocardiogram (ECG)

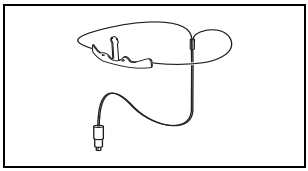
  In the ECG, the electrical voltages which occur between certain points of the skin as a consequence of cardiac excitation are registered. SOMNO*lab* 2 enables changes to or disorders of cardiac rhythm to be detected.

Respiratory flow snore sensor 17



The respiratory flow snore sensor allows you to record your patient's nasal and oral respiratory flow and snoring noises.

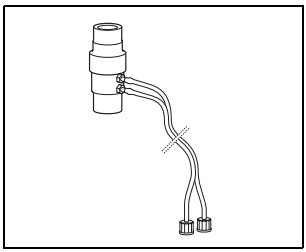
- The sensor beads consist of thermistors. They detect respiratory flow by means of the temperature difference between exhaled and inhaled air.
- The microphone registers the patient's snoring noises.



Respiratory flow oral sensor 28

The respiratory flow oral sensor enables you to record your patient's oral respiratory flow for diagnosis with the respiratory flow nasal cannula and to set or check therapy.

- The sensor beads consist of thermistors. They detect respiratory flow by means of the temperature difference between exhaled and inhaled air.



Pneumo-T-adapter 31

The Pneumo-T-adapter is used to check therapy in combination with a nasal cannula. It registers the respiratory flow and the snoring of your patient

during therapy and measures the therapy pressure prevailing in the mask.

- Pressure fluctuations on inspiration and exhalation are passed from the mask to the device through the pressure measurement tubes. Exhaling air generates a slight overpressure, whilst inhaling it accordingly produces a vacuum. Respiratory breaths can be deduced from the differences in pressure.
- Snoring noises are measured via rapid changes in pressure.
- Therapy pressure is deduced from the static component of the pressure signal.

The function of non-medical devices

Note that all non-medical devices must be installed outside the patient environment, i. e. at a distance of at least 1.5 m.

Network USB server

This USB server enables you to operate SOMNO*lab* 2 through a network. This is required in many sleep laboratories if the patient's room is at a distance from the recording room. You can likewise connect SOMNO*lab* 2 by cable via the USB/PC electrical isolation module.

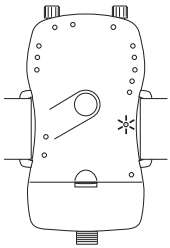
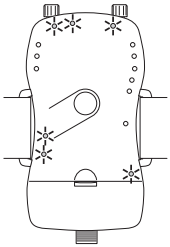
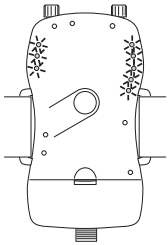
Note that the network USB server has to be installed outside the patient's environment.

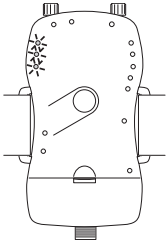
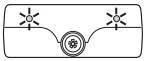
Card reader unit for CompactFlash cards

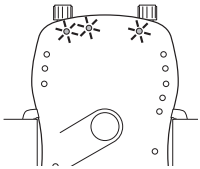
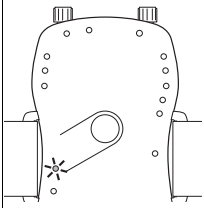
The card reader unit for the CompactFlash card enables you to read out SOMNO*lab* 2 data stored on the CompactFlash card. You can also configure SOMNO*lab* 2 via the card reader unit for the CompactFlash card and set up several CompactFlash cards of different configurations for yourself.

1.3 Signals and messages

In order for you to be able to be sure at all times that measurement is proceeding smoothly, SOMNO*lab* 2 has visual signals. These take the form of light-emitting diodes (LEDs).

Light-emitting diode		State	Meaning
LEDs on the memory card		Illuminated, bright green	Device is switched on.
		Flashing slowly, green (1x per sec.).	Wireless connection created (not on the SOMNO*lab* 2 effort).
		Flashing 10x, green (2x per sec.).	Start of recording.
		Flashing rapidly, green (4x per sec.).	Device being configured or stored measurement transferring to PC.
		Illuminated, yellow	No memory card in device.
		Flashing, yellow (2x per sec.).	Memory card full
LEDs on the respiratory inputs		Flashing, green (1x per sec.).	No sensor signal.
LEDs on electrodes (not on the SOMNO*lab* 2 effort)		Flashing rapidly (4x per sec.).	Impedance being measured.
		Goes out after impedance measurement.	Impedance of electrode < 5 kΩ, OK.
		Flashing slowly (1x in 2 sec.).	Impedance of the electrode < 10 k, not ideal but acceptable quality.
		Flashing (1x per sec.).	Impedance of electrode > 10 kΩ (check electrode, unacceptable signal quality)

Light-emitting diode		State	Meaning
		3 LEDs on left continuously illuminated.	Battery life < 6 h or less than configured measuring time. Battery should be charged.
All LEDs on device		Off.	Device switched off or recording in progress.
LEDs on battery		No LED illuminated.	Battery is not connected to the electricity supply.
		Left-hand LED illuminated, green.	Battery is connected to the electricity supply.
		Right-hand LED illuminated or flashing yellow.	Battery being charged.
		Left-hand LED illuminated, green, right LED off.	Battery full

Light-emitting diode		State	Meaning
Only with PSG (R&K) or PSG (AASM): During impedance measurement: all three LEDs of the respiratory inputs flashing simultaneously	 **Note** Impedance values of the electrodes can be called up in the SOMNO*lab* software.	Flashing rapidly (4x per sec.).	Impedance of electrodes on R&K or AASM master cable being measured
		Goes out after impedance measurement.	Maximum of one of the electrodes on the R&K or AASM master cable has 5-10 kΩ, not ideal, but acceptable signal quality.
		Flashing slowly (1x in 2 sec.).	Several electrodes on R&K or AASM master cable have 5-10 kΩ, no electrode > 10 kΩ, not ideal, but acceptable quality.
		Flashing (1x per sec.).	At least one electrode on the R&K or AASM master cable has over 10 kΩ check electrode, unacceptable signal quality)
		The LED of the corresponding signal stops flashing once the impedance test is complete.	Impedance of the electrode in question < 5 kΩ, OK or sensor signal present.
Only with PSG (R&K) or PSG (AASM): During the impedance measurement, the LED on the ECG master cable connection flashes.	 **Note** Impedance values of the electrodes can be called up in the SOMNO*lab* software.	Flashing rapidly (4x per sec.).	Impedance of electrodes on ECG master cable being measured
		Goes out after impedance measurement.	Maximum of one of the electrodes on the ECG master cable has 5-10 kΩ, not ideal, but acceptable signal quality.
		Flashing slowly (1x in 2 sec.).	Several electrodes on ECG master cable have 5-10 kΩ, no electrode > 10 kΩ, not ideal, but acceptable quality.
		Flashing (1x per sec.).	At least one electrode on the ECG master cable has over 10 kΩ (check electrode, unacceptable signal quality)

Note
If poor impedance is measured for the R&K or AASM master cable and the ECG master cable (> 10 kΩ), the LEDs on the device do not indicate which of the individual electrodes has poor impedance. In this case, call up the values for the individual electrodes via the SOMNO*lab* PC software in order to establish the faulty electrode.

1.4 Measuring conditions

- Follow the instructions for use on attaching the sensors/the accessories.
- Contamination of the sensors, by secretions, electrode paste residues or moisture, for example, can lead to faulty measurements.
- If the instructions for use are observed, the product is not sensitive to environmental effects.

Pulsoximetry sensor

- Ensure that the LEDs and the receiver in the sensor are not dirty or moist.
- The pulsoximetry sensor is calibrated to pulsoximetric hemoglobin oxygen saturation (assuming blood is free of dysfunctional hemoglobin) by means of referenced measurements obtained from fractional saturation measurement. Functional oxygen saturation of arterial blood is determined with the aid of the pulsoximetry sensor on the patient's finger, in other words, non-invasively. If the proportion of dysfunctional hemoglobin (e.g. carboxyhemoglobin or methemoglobin) is high, this will impair measurement accuracy.

- Faults in the measurement signal are monitored by the device. The device issues error messages when the faults are outside the internally specified limits. The device then restricts its measuring mode. "0" values are displayed.
- Normal ambient light is compensated by the sensor. Particularly strong or fluctuating ambient light, e.g. as a result of direct sunlight or operating room lights, may falsify measuring results. The device then restricts its measuring mode. "0" values are displayed.
- There may be a negative impact on pulsation strength. This may be the case, for example, when blood pressure cuffs or arterial catheters are used, in the case of arterial occlusion or if the sensor is attached too tightly.
- The device detects movement artifacts, suppresses the majority with the aid of various algorithms and issues a message as soon as they become too high. It is not possible to rule out false measured values being displayed if movement artifacts persist for a prolonged period.
- With a high proportion of dysfunctional hemoglobins (e.g. carboxyhemoglobin or methemoglobin), measurement may deliver a normal result, even if the patient is hypoxic.
- Intravascular dyes such as methylene blue, indocyanine green or other dyes will significantly falsify the measuring result.
- False nails made of acrylic, or colored nail varnish may affect measurement accuracy and should be removed before the start of the measurement.

Respiratory flow snore sensor

Note
If the sensor is covered by a blanket, ambient temperature will rise to body temperature which may cause faulty measurements.

- Measurement of the respiratory flow curve is based on measurement of the difference in temperature between the flow of inhaled and exhaled air. As a result, an inadequate signal is detected if ambient temperature is between 33 °C and 38 °C.
- Sensor beads **18** must be precisely located in the nasal and oral air flow.
- The sensor beads may not be coated with contamination such as secretions, otherwise incorrect measurements may result.
- The sensor may only be used again after being dried completely.
- The membrane over microphone **20** may not be damaged.
- In addition to the patient's snoring noises, the microphone of the respiratory flow snore sensor also registers ambient noises at typical snore frequencies. Ensure that the ambient volume is much lower than the volume caused by snoring noises.
- You can use the respiratory flow snore sensor in combination with the respiratory flow nasal cannula.

Respiratory flow oral sensor

Note
If the sensor is covered by a blanket, ambient temperature will rise to body temperature which may cause faulty measurements.

- Measurement of the respiratory flow curve is based on measurement of the difference in temperature between the flow of inhaled and exhaled air. As a result, an inadequate signal is detected if ambient temperature is between 33 °C and 38 °C.
- The sensor bead must be precisely located in the oral air flow.

- The sensor bead may not be coated with contamination such as secretions, otherwise incorrect measurements may result.
- The sensor may only be used again after being dried completely.
- You can use the respiratory flow oral sensor in combination with the respiratory flow nasal cannula.

Respiratory flow nasal cannula

- The respiratory flow nasal cannula is used as an alternative to the thermistor with microphone (respiratory flow snore sensor).
- The respiratory flow nasal sensor is for diagnosis measurement, it cannot be used simultaneously with the Pneumo-T-adapter for xPAP measurements.
- The difference between nasal pressure and ambient pressure is detected.
- Large quantities of secretion (colds) or blood (nosebleeds) may impair the measurement of respiratory flow and snoring.
- External noises (e.g. traffic) may impair snore measurement.
- The respiratory flow nasal cannula must be connected directly to pressure measurement connection **B**. If you select the wrong connection, you will obtain incorrect measuring results in the respiratory flow and for snore detection. Cardiorespiratory analysis will no longer work properly.
- Do not use damaged nasal cannulas.
- The tube may not be pinched during the measurement.

- The respiratory flow nasal cannula is a disposable item.
- To obtain correct measuring results, also open the second pressure connection during the measurement.

Snore detection

Note
Snore detection generally only works correctly if it is correctly configured in the SOMNO*lab* PC software. If necessary, check the settings in the PC software before performing snore detection. See also online Help relating to the SOMNO*lab* PC software.

This is effected primarily from the respiratory flow nasal cannula. If snoring is to be detected from the respiratory flow snore sensor, the respiratory flow nasal cannula must be deactivated. If a Pneumo-T-adapter is connected, snore detection is automatically performed from the Pneumo-T-adapter.

Pneumo-T-adapter

- The Pneumo-T-adapter is used when making therapy settings and checking therapy in combination with xPAP devices.
- The Pneumo-T-adapter can be used in combination with the respiratory flow oral sensor to enable oral respiration to be detected.
- Large quantities of secretion (colds) or blood (nosebleeds) may impair the measurement of respiratory flow and snoring.
- Ensure that the pressure measurement tubes are correctly connected on the Pneumo-T-adapter and the device. If the tubes are confused, inspiration and exhalation will be shown the wrong way round in the recording.
- The Pneumo-T-adapter and the pressure measurement tubes must be clean and free of fluid.
- The pressure measurement tube may not be kinked.

- The Pneumo-T-adapter should be attached securely and tightly to the mask.
- The internal measurement tube of the therapy device should not pass through the Pneumo-T-adapter, otherwise measurement will be inaccurate.

Position sensor in SOMNO*lab* 2

The position sensor integrated in the device only works properly if SOMNO*lab* 2 is attached with the aid of the belts in accordance with these instructions for use, otherwise faulty measurements may occur.

Thorax sensor

Two thorax sensors are integrated in the device with protection. These sensors detect respiratory movements of the thorax. They are made of a skin-friendly synthetic material. The T-belt is for attaching the thorax sensors and the device to the patient's body.

- The T-belt marked yellow is manufactured to a normal size, that marked green to an extra-large size. Select the belt suitable for your patient.
- Ensure that the belt is adequately tight when the sensors are put on. Inadequate tension may lead to loss of signal amplitude or complete signal failure. The belt may not cause chafing, however. Your patient must still be able to breathe freely.
  The belt is made of a skin-friendly elastic fluffy tape.

Abdomen sensor

Use the abdomen sensor in combination with the abdominal belts. The abdomen sensor detects respiration movements of the abdomen. The sensor is made of a skin-friendly synthetic material.

EXG electrodes (not on the SOMNO*lab* 2 effort)

The variable recorded by the electrodes is voltage. The difference in voltage between two points of the body is measured. As the measurement is performed non-invasively on the surface of the skin, measurable differences in voltage are very small. They are in the µV range for EEG, EOG and EMG and in the mV range for ECG.

A key factor in the quality of the measurement is the electrical resistance between the skin, the electrode and the gap between the two. Transitional resistance can be reduced by careful cleaning, removal of grease and slight roughening of the skin, as well as by the use of electrode gel.

The reference electrode (Z electrode) plays a key role in the leads. It ensures there is a common reference potential for the electronics.

2. Safety instructions

Read these instructions for use through carefully. They are a constituent part of the device and must be available at all times. Use the device only for the intended use described (see "1.1 Intended use" on page 11).

For your own safety and that of your patients, and in accordance with the requirements of directive 93/42/EEC, observe the following instructions.

SOMNO*lab* 2 and application parts

Warning!

- The battery may not be damaged, crushed, opened or taken out of its case.
- Keep the battery away from heat, naked flame and corrosive liquids.
- Before a defibrillator is used, all parts of the system on the patient must be removed completely.
- SOMNO*lab* 2 may not be operated in an atmosphere at risk of explosion.
- When SOMNO*lab* 2 is connected to the electricity supply via other devices (e.g. via the electrical isolation module), do not operate SOMNO*lab* 2 during a thunderstorm, if there is any risk at all to the device or the patient.
- Before cleaning SOMNO*lab* 2, disconnect the power supply plug, the battery and all the power supply plugs of devices connected to SOMNO*lab* 2.
- Do not connect the device to the electricity supply with the aid of electrode cables or connectors.

- Do not touch the patient if you are simultaneously holding the connector for the power supply unit and the power supply unit is still connected to the power supply socket.
- The device must not be modified. If you modify the device, you are considered a system configurer, and are therefore responsible for compliance with the applicable version of standard EN 60601-1. In the event of questions, contact your local specialist dealer or Weinmann Customer Service.
- Do not touch the patient if you are in contact with electrically conductive parts of other devices that are not application parts.

Caution!

- Do not short-circuit the battery.
- The system may not be used to monitor vital physical functions.
- The device is not intended for use on people weighing less than 20 kg.
- SOMNO*lab* 2 may not be used on the open heart.
- The system generates information signals. These are for checking the presence of signals for recording and to check the function of the device. Alarms are not generated.
- The PC on which the data are stored and visualized, its peripherals (e.g. printer) or non-medical devices may not be placed in the immediate vicinity of the patient (within 1.5m).
- Additional equipment connected to the analog and digital ports of the device must have evidence of conformity with the corresponding EN specifications (e.g. EN 60950 for data processing devices and EN 60601 for electrical medical devices). Furthermore, all configurations must comply with the version of system standard

EN 60601-1 applicable at the time of sale. Anyone connecting additional devices to the signal input or output part is considered a system configurer and is thus responsible for compliance with the applicable version of standard EN 60601-1. In the event of questions, contact your local specialist dealer or Weinmann Customer Service.

- Follow the instructions for use and the short-form instructions for use of existing older system components which you want to use with SOMNO*lab* 2.
- SOMNO*lab* 2 may only be used by trained professionals with adequate factual knowledge who have received instruction.
- If third-party items are used, functional failures may occur and fitness for use may be restricted. Biocompatibility requirements may also not be met. Please note that in such cases, any claim under warranty and liability will be voided if neither the accessories nor genuine replacement parts recommended in the instructions for use are used.
- SOMNO*lab* 2 components may not be immersed in liquids. Ingress of liquid into the device during operation and storage reduces the functional capability and safety of the device.
- The battery may not be immersed in liquids, either. Gas may evolve and the battery may split!
- Replace all parts which are damaged, worn or contaminated before using the device.
- Only the manufacturer or informed staff may open the device and carry out repairs or servicing work. Any claim under warranty is voided if the device is opened without authorization.

- Operate the device only in conjunction with the original Weinmann power supply unit.
- Do not operate any devices which produce electromagnetic fields in the vicinity of SOMNO*lab* 2. Faults or measuring errors may be caused by the following devices, for example:
  - interference with an electrical surgical unit
  - X-rays
  - MRI devices
  - radio signals (radio telephones, cellphones …)
  - power lines
  - electrical stimulation devices
- Do not operate SOMNO*lab* 2 with devices which supply the body with energy, such as electrostimulation devices, for example. SOMNO*lab* 2 may be used on patients with cardiac pacemakers.
- The device may only be operated and stored under the ambient conditions stated in the technical data.
- Please comply with section "7. Hygiene treatment" on page 68 to prevent infection or bacterial contamination.
- Plug all sensor connectors into the specified connection points.
- Ensure that sensors and sensor cables are applied in accordance with specification. Incorrectly attached sensor cables may lead to injuries.
- If you are using an electrical isolation module, route the connecting lead in such a way as to avoid injury to the patient.
- The device may deliver incorrect measuring results if drugs which change blood color or measured physiological parameters are taken.

- If you are using multiple sockets, only connect the SOMNO*lab* 2 polygraphy system to them. If you are using SOMNO*lab* 2 as part of a mobile sleep diagnosis (SOMNO*mobil*) system, do not use any additional multiple sockets. Please note the instructions for use of the mobile sleep diagnosis (SOMNO*mobil*) system.
- Multiple sockets which are used in a variety of locations may not be placed on the floor.
- Do not use an extension cable to connect SOMNO*lab* 2.
- The electrodes applied to the patient have electrical contact with other conductive parts of the application part. The electrodes may not have contact with any other conductive parts which do not belong to SOMNO*lab* 2.
- Do not connect any third-party devices to SOMNO*lab* 2 (e.g. devices with 1.5 mm plugs).
- Be aware that a safe distance needs to be maintained between SOMNO*lab* 2 and devices which emit HF radiation (e.g. cellphones), otherwise there might be malfunctions (see "13.1 Safety distances" on page 90).
- This device requires special precautionary measures as regards electromagnetic compatibility (EMC). Only install it and put it into operation in accordance with the EMC instructions in the accompanying documentation (see "13.1 Safety distances" on page 90).
- Other devices may interfere with SOMNO*lab* 2, even if these other devices conform to the valid CISPR emissions requirements.
- Do not use SOMNO*lab* 2 immediately next to other devices, and do not stack SOMNO*lab* 2 with other devices during operation.

- Use of accessories and cables other than those stated may lead to increased emission or reduced immunity to interference of the device or system.
- SOMNO*lab* 2 and its associated parts may not come into contact with injured, damaged and/or infected skin when being attached to the patient.

Note

- Dispose of the accessories in accordance with the regulations applicable in your medical sphere.

SOMNO*lab* PC software

Note

- See the online Help contained in the PC software. No software other than the SOMNO*lab* PC software may be installed or operated on the computer unless it has been approved for this use by Weinmann.

3. Combination with therapy systems

3.1 Devices

You can combine SOMNO*lab* 2 with common CPAP, BiLevel and APAP therapy systems to form a control system. The two systems are quick and easy to couple up via the Pneumo-T-adapter which is plugged between the tube and the mask.

Note The Pneumo-T-adapter of SOMNO*lab* 2 has been tested with all Weinmann therapy devices. If third-party devices are used, the increased flow resistance may lead to restricted trigger function.

3.2 Masks

Important!
You should also follow the instructions for use for the mask.

You can combine SOMNO*lab* 2 with the masks commonly used in sleep apnea applications. These must have a EN ISO 5356-1 connection.

4. Installation

4.1 Install the driver for data transfer via the network USB server

Follow the instructions for use for the USB server.

Our hotline is available for installing the USB server.

4.2 Install driver for the card reader unit for CompactFlash cards

Follow the instructions for use for the card reader unit for CompactFlash cards.

Our hotline is available for installing the card reader unit for CompactFlash cards.

4.3 Prepare connection of SOMNO*lab* 2

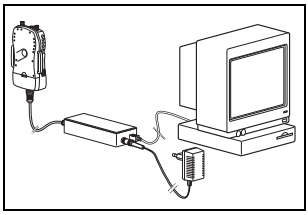
Connect USB/PC electrical isolation module 40 to PC (for cable communication)

The electrical isolation is to protect the user/the patient. The USB/PC electrical isolation module must always be used if there is communication with the PC or the battery is being charged.

Note
The PC system must be switched off when the USB/PC electrical isolation module is connected up.

1. Plug USB cable **39** into connection **42** (marked **C**) on the USB/PC electrical isolation module, the other end into a free USB port on the PC.

   If you have several SOMNO*lab* 2 systems, ensure correct assignment to the individual devices.



2. Plug connector **37** of the power supply unit into connection **43** (marked **B**) on the USB/PC electrical isolation module.
3. Plug one end of the charging/data transfer cable into connection **8** on the battery, the other end into connection **41** (marked **A**) on the USB/PC electrical isolation module.
4. Plug the connector of the power supply unit into a power supply socket.

Note
The connector of the charging/data transfer cable is equipped with a latching mechanism to prevent the cable being pulled out inadvertently. To remove the cable from the USB/PC electrical isolation module again, first push the outer sleeve of the connector backwards in order subsequently to be able to pull out the connector.

Save yourself work. Leave the power supply unit permanently plugged into a power supply socket and the USB cable connector plugged into your PC. This means the connector for SOMNO*lab* 2 is always handy on your desk.

The system is now operational.

Connect network USB server to PC (for communication via network)

- Connect the USB server to the network as described in its instructions for use.
- Now plug the USB connector of the converter cable into the USB port of the USB server.
- Commissioning should be performed by a Weinmann product specialist for SOMNO*lab*. Contact our hotline for this (see Page 78).

Connect card reader unit for CompactFlash cards

Connect the card reader unit for CompactFlash card to the PC as described in the instructions for use for the card reader unit.

5. Operation

This section includes all the information you need to make it easy to operate the SOMNO*lab* 2 polygraphy system. Any applications and explanations within the SOMNO*lab* PC software and the higher-level SOMNO*manager* administrative program can be obtained from online Help which contains a user manual you can print out. This can be accessed via the menu item **? / Manual**. The user's manual of the SOMNO*lab* PC software can be found on the CD.

Note Application of the sensors, handling of the device and handling of the battery of SOMNO*lab* 2 are described in this and the next section. Read these sections through carefully.

The short-form instructions for use, "SOMNO*lab* 2 in 7 steps", and all the other instructions for use for SOMNO*lab* 2 can be printed out using the SOMNO*lab* PC software.

Using the SOMNO*lab* PC software

Please refer to the online Help or user's manual for operation and information about the software.

Among other topics, the online Help and user's manual describe the following:

- how to prepare and configure the device for outpatient and inpatient measurement
- how to configure and set the display
- the course of the measurement
- evaluation of the measurement

Before you give your patient the SOMNO*lab* 2, you can double-check by querying status whether all settings and the current time of the SOMNO*lab* 2 are correct. Check all settings. If you discover incorrect settings, program SOMNO*lab* 2 again.

Notes

- Each time SOMNO*lab* 2 is reprogrammed, the clock time in the basic device is compared to the system clock time of your PC. It is therefore important that the time is set correctly on your PC, otherwise the recording will start at the wrong time.
- If data transfer to the PC is interrupted, the measured data are still stored in the device. The signals are shown as a zero line in the software. You can read out all the data the next day.
- Note that an incorrectly-set display configuration may lead to misinterpretations.
- Note that channels deactivated in the device configuration are not transmitted. The configuration of visualization does not affect archiving.
- If you are operating several devices, check that the basic device is correctly assigned to the PC.

5.1 Attach and position electrodes (not on the SOMNO*lab* 2 effort)

Note

- The battery must be charged before you use SOMNO*lab* 2. To do this, see the section entitled "6.1 Charge battery" on Page 64.
- The SOMNO*lab* PC software contains a diagram as an application guide for both master cable options (PSG (R&K) or PSG (AASM)) to help you position the electrodes. Call up the relevant diagram and print it out before continuing, if necessary. The application instruction for the PSG (R&K) option can be found under **? / SOMNO*check* 2 / SOMNO*lab* 2 / Electrodes R&K**. The application instructions for PSG

(AASM) can be found under **? / SOMNO*check* 2 / SOMNO*lab* 2 / Electrodes AASM**.

1. Call up the above-mentioned diagram in online Help and print it out if necessary.
2. First affix all adhesive/gold cup electrodes to the right places on your patient's body – as described in the following sections.
3. Use the press studs to attach the electrode cables to the electrodes. Observe the color-coding on the application instructions and on the rear of the device.
4. Then plug the connectors of the electrode cables into the matching-colored sockets of SOMNO*lab* 2 or of the master cable **(only with PSG (R&K) or PSG (AASM))**.

   Do not affix the electrodes too close together, otherwise the cables will short-circuit. They will then no longer be able to receive a signal.
5. Plug the R&K or AASM master cable into the socket provided **(only with PSG (R&K) or PSG (AASM))**.
6. Plug the ECG master cable into the socket provided **(only with PSG (R&K) or PSG (AASM))**.

Notes

- Perform an impedance measurement of the electrodes as a function check before each recording.
- Do not connect any electrodes in parallel to other systems. The function of SOMNO*lab* 2 is then no longer guaranteed.
- Ensure that the electrodes are correctly connected, otherwise you will get false analysis results and signal displays.
- Do not connect any third-party devices with 1.5 mm connectors to SOMNO*lab* 2.

Affix gold cup electrodes

1. Clean the desired skin location with physiological saline (NaCl 0.9 %) or alcohol. A cotton wool ball and/or gauze swab is highly suitable.
2. Then roughen the skin with a skin preparation paste. Rub a little conductive paste into the skin using a finger; this promotes conductivity and provides a good surface for the electrode to adhere to.
3. Then put a pea to bean-sized piece of conductive paste into the depression in the electrode and press the electrode firmly to the skin so that the paste is squeezed out from under the edges.
4. Place a piece of gauze over the electrode and the escaped paste and press on again. Ensure that the edge of the electrode is firmly attached to the skin, sealing off the conductive surface. This will prevent the paste in the electrode losing conductivity as a result of drying out.
5. Also fix the cable of the electrode with a plaster. This relieves tension and ensures reliable recording overnight.

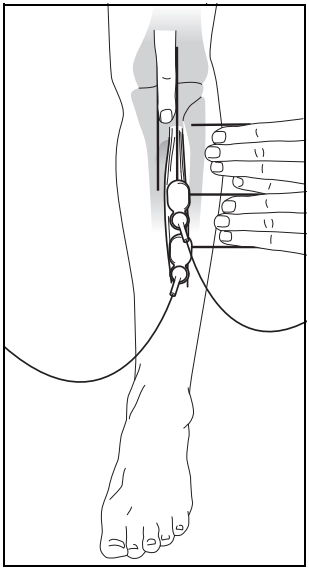
With the EMGs, you can also use disposable electrodes. To do so, clean the skin as for gold cup electrodes and also fix the electrodes with plasters.

Notes

- Apply the electrodes very carefully. The quality of the measurement depends on a good adhesion point, as the transition point between the skin and the electrode is highly susceptible to faults. Poorly-affixed electrodes increase artifacts, making the recording harder to assess. Clean the electrodes with alcohol or saline before every measurement.

- Follow the instructions for use for the adhesive electrodes, gels and pastes with regard to skin tolerance and allergies to the materials used.
- Observe the shelf life of the gels, pastes and electrodes used.

Positioning the leg EMG

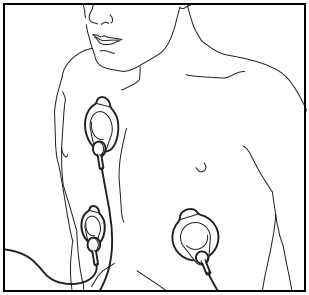


The leg EMG is recorded on a bipolar basis.

The first lead point is 4 finger-widths below the attachment of the patellar ligament and one finger-width lateral of the proximal margin of tibia; the second point is 5 cm distal of this. You can also use disposable electrodes for the leg EMG. To do so, clean the skin as for the gold cup electrodes.

Fix the electrode cable with plasters in several places. This will prevent the cable dropping off as a result of the patient's movements.

Positioning the ECG



Like EMGs, the ECG is also recorded on a bipolar basis. The polysomnography lead of SOMNO*lab* 2 is analogous to the Einthoven lead. To this end, affix the negative electrode marked red to the sternal attachment of the 2nd rib on the right and the positive electrode marked yellow or green to the apex of the heart.

In addition to the recording electrodes, a further earth electrode should be attached as an electrical reference. The black reference electrode is affixed as shown in the adjacent drawing.

Use the enclosed disposable adhesive electrodes to affix the ECG. The skin is cleaned as for the other electrophysiological signals. Fix the electrode cable in position with a plaster. This will prevent the cable dropping off as a result of the patient's movements.

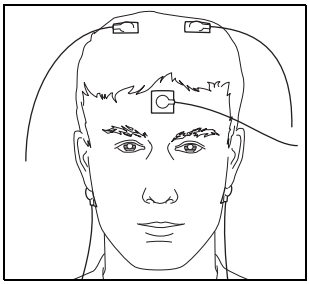
Position EEG electrodes

In order to perform a proper sleep recording, the EEG electrodes are fixed in accordance with the 10:20 system.

In addition to the EEG electrodes, an additional earth electrode must be affixed to the forehead as an electrical reference (Z).

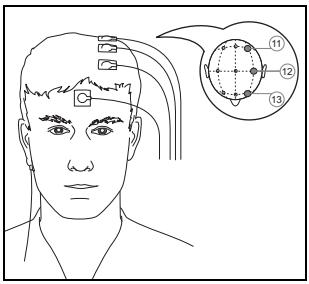
Tip Use the mastoid electrodes (M1/M2) as reference. These are easier to affix and are not as susceptible to faults as the ear electrodes (A1/A2).

RECHTSCHAFFEN and KALES EEG



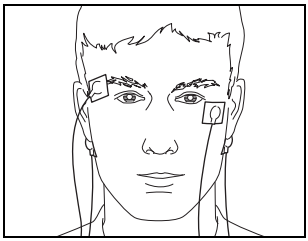
To register the EEG during sleep, you need leads C3 and/or C4. Use the ear or mastoid electrodes of the opposite side as reference electrodes. This gives you leads C3 - A2/M2 and/or C4 – A1/M1.

AASM 2007 EEG



To register the EEG during sleep, you need leads O1, C3 and F3. Use the ear or mastoid electrodes of the opposite side as reference electrodes. This gives you leads O1-A2/M2, C3-A2/M2 and F3-A2/M2.

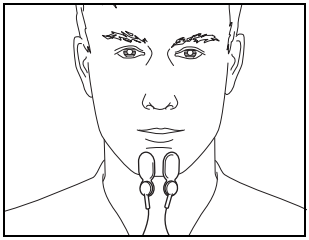
Position EOG electrodes



SOMNO*lab* 2 has two channels for recording eye movements. Position one electrode approx. 1 cm above and somewhat to the side of the edge of the right eye. The reference electrode is located on the mastoid or earlobe on the same side. Affix the second electrode approx. 1 cm below and again somewhat to the side of the edge of the left eye. The reference is the ear or mastoid electrode on the same side.

This arrangement records the EOG signals in counterphase in both REM sleep and when awake. Artifacts and EEG signals are shown in parallel phase with this arrangement.

Electromyogram (EMG)



The EMG registers muscle activity at the chin/legs. The EMG is for recording physiological and pathological movement activity of the body or of individual extremities.

Note: The EMG on the chin is required to distinguish the different stages of sleep. The EMG of the legs is specifically for diagnosing "restless legs syndrome" (RLS) and "periodic leg movement in sleep" syndrome (PLMS).

5.2 Put on SOMNO*lab* 2 device and sensors

Notes

- Ensure that all belts, sensors and cables are attached to the patient so that they cannot cause any chafing or restrict breathing. Your patient must still be able to breathe freely.
- It is essential to charge the battery before using the device for the first time.
- Your patient should put the sensors on him or herself under your instruction.

Application instructions

When you program SOMNO*lab* 2 it is possible to print out the programmed configuration under **Extras / Application Diagram**.

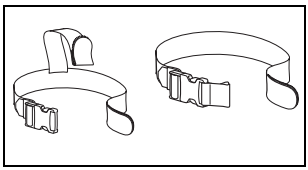
The printout contains a diagram of the configuration.

Instructions for use for the patient

You can print out the instructions for use for the patient in the corresponding language in the SOMNO*lab* PC software under **? / SOMNO*check* 2 / SOMNO*lab* 2 / Patient Guide**.

Note

SOMNO*lab* 2 and its associated parts may not be brought into contact with injured or infected skin. Dress any wounds with a stable dressing beforehand. Instruct your patient to wear pajamas under the system.



The scope of supply includes different belts, **45** and **46**. The belts marked yellow are manufactured to a normal size, those marked green to an extra-large size.

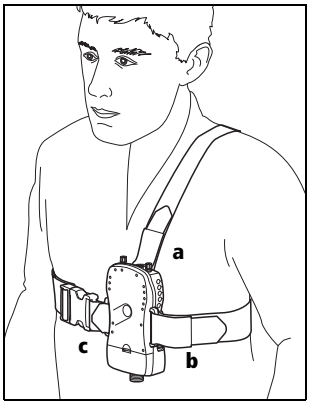
Select the belt suitable for your patient. Ensure that the colored ends of the belt are on the right-hand

side of the body. Use the attachment belt to attach the SOMNO*lab* 2 basic device to your patient's body.

Attach the device

Note
On the rear of the SOMNO*lab* 2 are application instructions which will help you connect sensors and/or electrodes correctly. Once the device has been attached to the body, however, this application instruction is no longer visible, so always attach the adhesive electrodes and the electrode cables to the body before you put on the device.

1. First thread the belt through upper eye **a** and then through eye **b** on the side of the device.
2. Hang the loop of belt thus formed over your patient's shoulder.
3. Now draw the short connecting piece with the snap-fit buckle through remaining free eye **c** and close the belt using the buckle.
4. You can adjust the belt to suit the dimensions of your patient's body by adjusting the Velcro tapes. It should be firm, but comfortable on the body.



Notes

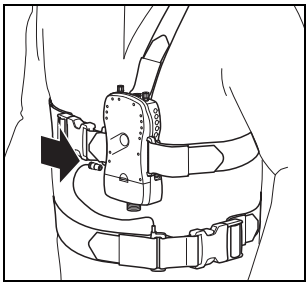
- Ensure that the device is secure. It should be in the center of the chest (sternum).
- Fix the device firmly but comfortably to your patient. Only then will the sensors integrated in the device work reliably. Otherwise faulty measurements may occur.

- Ensure that the belt is always taut on the body and that the sensors and cables are correctly attached, but do not cause chafing. Your patient must still be able to breathe freely.
- Make it as easy as possible for your patient. Put the SOMNO*lab* 2 system on your patient "as a trial". Show him/her and explain clearly how to put on the sensors in the evening without your help. The procedure for putting on the sensors and the device is explained in the instructions for use for the patient.
- Undo just the snap-fit buckle on the side of the belt to take the SOMNO*lab* 2 polygraphy system off your patient again. Give your patient the SOMNO*lab* 2 polygraphy system to take in the carrying bag. This protects the device and the sensors. Ensure that the battery is charged before you put the SOMNO*lab* 2 polygraphy system on your patient and give it him/her for measurement.
- The belt is made of a skin-friendly elastic fluffy tape.

Put on abdomen sensor

- Abdominal belt **46** is for attaching abdomen sensor **33** to your patient's body.
- The abdominal belt marked yellow is manufactured to a normal size, that marked green to an extra-large size. Select the belt suitable for your patient.
- The belt may not cause chafing. Your patient must still be able to breathe freely. The belt is made of a skin-friendly elastic fluffy tape.
- Use abdomen sensor **33** in combination with the abdominal belts. The abdomen sensor detects abdominal movements of respiration.

Abdomen sensor

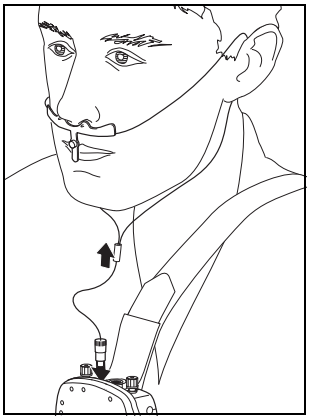


1. Draw the short connecting piece with the snap-fit buckle through the eye of the sensor.
2. Place the abdominal belt round the patient's abdomen and pass the abdominal belt through the other eye of the sensor.

   The sensor must be on the center of the abdomen.
3. Close the belt using the buckle.
4. Ensure that the belt is always taut on the body, otherwise the respiratory movements may not be detected.
5. Connect the sensor to connection **4** on the device.

Attach respiratory flow snore sensor

The respiratory flow snore sensor is used for diagnosis.

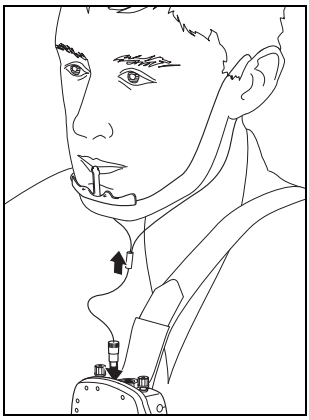


1. Unwind the sensor from carrier plate **21**. Place the sensor on your patient’s top lip. Ensure that the microphone is on the side facing away from the skin, remaining visible.
2. Pass the cable over the ears and tighten under the chin by pushing up the sleeve.
3. Connect the plug of the respiratory flow snore sensor to the round connection **16** on the top of the device.
4. Seal off pressure connections **1** and **10** using the enclosed stoppers.
5. After the measurement, place the sensor back on the carrier plate to prevent it becoming kinked and wind the cable around the sensor and the carrier plate.

   The carrier plate can be cleaned and disinfected like the sensor.

Attach respiratory flow oral sensor

Use respiratory flow oral sensor **28** in combination with respiratory flow nasal cannula **23** for diagnosis or in combination with Pneumo-T-adapter **31** to check therapy/set therapy to detect respiration through the mouth.



1. Unwind the sensor from the carrier plate. Place the sensor on your patient's bottom lip.

   Ensure that the sensor beads are pointing towards the oral cavity.

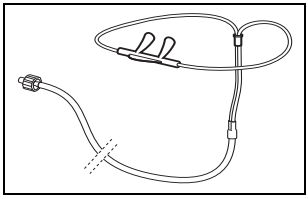
2. Pass the cable over the ears and tighten under the chin by pushing up the sleeve.
3. Connect the plug of the oral thermistor to connection **16** on the top of the device.
4. Seal off pressure connections **1** and **10** using the enclosed stoppers.
5. After the measurement, place the sensor back on the carrier plate to prevent it becoming kinked and wind the cable around the sensor and the carrier plate.

   The carrier plate can be cleaned and disinfected like the sensor.

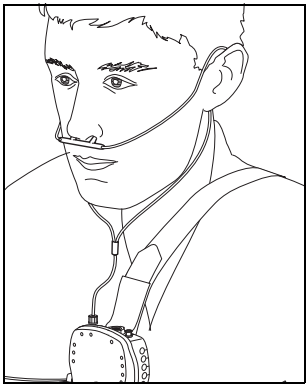
Attach respiratory flow nasal cannula

The respiratory flow nasal cannula is used for diagnosis.

Note You can use respiratory flow nasal cannula **23** simultaneously with respiratory flow oral sensor **28**.



1. Remove the two protective stoppers (if present) from pressure connections **1** and **10** on SOMNO*lab* 2 and screw the tube of the nasal cannula onto connection **B** marked with the nasal cannula.



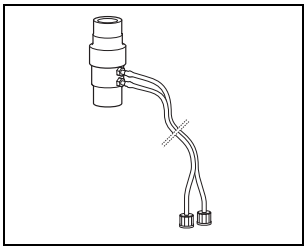
2. Grasp the double tube to the left and right so that the cannulas point upwards.
3. Now position the cannulas in the nostrils and guide the tubes along behind the ears and under the chin. Align the sleeve at the fork so that the tube is loose but does not slip out of position.

Tip Greasing the nostrils slightly, with Vaseline for example, can increase wearing comfort and prevent drying out.

Attach Pneumo-T-adapter

Pneumo-T-adapter **31** is used when making therapy settings and checking therapy in combination with xPAP devices.

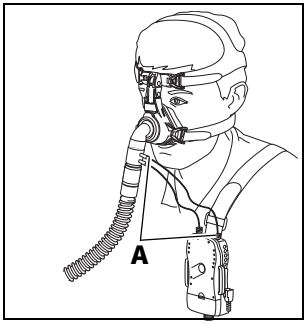
Note The Pneumo-T-adapter can be used in combination with respiratory flow oral sensor **28** to enable oral respiration and oral leakages to be detected.



1. Ensure that the mask has an integrated exhalation system. If a mask without an integrated exhalation system is used, a separate exhalation system must be used in addition. In this case it is also important to follow the instructions for use for the exhalation system.
2. Connect the soft end of the Pneumo-T-adapter to the external exhalation system of the mask.
3. Now connect the breathing tube to the hard side of the Pneumo-T-adapter. The internal measurement tube of the therapy device should not pass through the Pneumo-T-adapter,

otherwise you will obtain inaccurate measurements.

4. Push the ends of the double tube onto the connecting stubs of the Pneumo-T-adapter as follows:
   - the tube marked red onto connection **A** of the adapter (likewise marked red)
   - the other tube onto connection **B**.

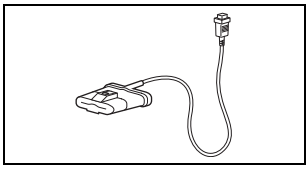


5. Screw the tube plugged onto the connection nearer to the breathing mask (marked red) of the adapter to pressure connection **A** on the device.
6. The other tube is accordingly screwed onto the other pressure connection.

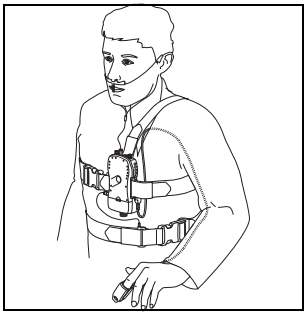
Ensure that the pressure measurement tubes are correctly connected on the Pneumo-T-adapter and the device. If the tubes are confused, inspiration and exhalation will be shown the wrong way round in the recording.

Important Connection **A** of the Pneumo-T-adapter which points towards the mask must **always** be connected to **A** on the device, otherwise the respiration phases will be shown incorrectly in the software.

Attach pulsoximetry sensor



- Use the pulsoximetry sensor only in combination with SOMNO*lab* 2.
- If you are simultaneously monitoring your patient's blood pressure with a cuff, do not attach the pulsoximetry sensor to the arm to which the cuff is attached.

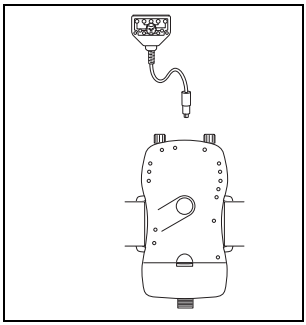


1. Attach the pulsoximetry sensor to one of your patient's index fingers.

   Ensure that the finger marking on the sensor is pointing upwards. The sensor should be comfortably and securely positioned. It should not squeeze the finger.

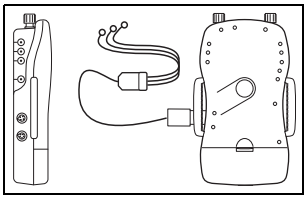
Note
No adhesive tape may be attached to the sensor housing.

2. If required, fix the sensor in position by attaching the sensor cable firmly to the finger with adhesive tape, for example.
3. Plug the sensor connector into socket **12** on SOMNO*lab* 2. Ensure that the connector is firmly located.



Attach R&K or AASM master cable (only with PSG (R&K) or PSG (AASM))

1. Affix the electrodes for the EEGs and EOGs as described from Page 48.
2. Plug the connector for the R&K or AASM master cable into connection **13**.



Attach ECG master cable (only with PSG (R&K) or PSG (AASM))

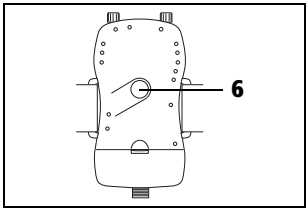
1. Affix the electrodes for the ECG as described from Page 47 onwards.
2. Plug the connector for the ECG master cable into connection **3**.

Tip: Use the ECG master cable extension contained in the set as the connection between the ECG master cable

and the device. Leave the extension plugged into the device for easier handling.

Perform a sensor test (not on the SOMNO*lab* 2 effort)

Perform a test once the sensors and devices have been attached to reassure yourself and your patient that all the sensors are properly connected.



- Start the sensor test/impedance measurement by pressing key **6** on SOMNO*lab* 2 twice in quick succession or by calling up the impedance measurement on the PC.
- You should also follow the instructions in the section entitled "1.3 Signals and messages" on Page 23.

Method	Device
Sensor test running	During the sensor test, the LED of the sensor just being tested flashes rapidly (4x a second).
Sensor test OK	The LED of the corresponding signal stops flashing once the impedance test is complete: impedance of the electrode < 5 kΩ OK or sensor signal present.
Sensor test acceptable	The LED of the corresponding signal flashes slowly once the impedance test is complete: impedance of the electrode < 10 kΩ, not ideal but acceptable quality. Green LEDs flash slowly (1x in 2 seconds).
Sensor test not OK	The LED of the corresponding signal flashes rapidly once the impedance test is complete: impedance of the electrode > 10 kΩ or no sensor signal (check electrode/sensor, unacceptable signal quality). Green LEDs flash rapidly (1x per second).

Note If poor impedance (> 10 kΩ) is measured for the R&K or AASM master cable and the ECG master cable,

the LEDs on the device do not indicate which of the individual electrodes has poor impedance. In this case, call up the values for the individual electrodes via the SOMNO*lab* software in order to establish the faulty electrode.

Once the electrodes/sensors have been attached successfully, the relevant LED on SOMNO*lab* 2 goes out. The state of the LEDs on SOMNO*lab* 2 does not then change again when the sensor test is ended in the next step by closing the impedance window in the software.

In the sensor test, all channels including effort and pulsoximetry sensors, as well as oral thermistor and nasal cannula, are checked for the presence of a signal. If the LED is off, this means: "Sensor is connected and transmitting a (physiological) signal".

An impedance test runs through all the configured channels once and then displays its result until the window is closed or a new test is started.

Notes

- Correct recording and performance of automatic analysis is possible only at a low impedance value. For optimum signal quality, we recommend aiming for a completely non-illuminated LED for all channels.
- For an application check on the PC screen, observe the plausibility of the signals. If a signal is not displayed, check device and display configurations. If both are present and you still receive no signal, this is an indication that the sensor is defective.

5.3 Start and end of measurement

Start and end of measurement for outpatient measurement

Switch on SOMNO*lab* 2 for configuration using the **6** key. The device automatically switches off again after 15 minutes if you do not perform any further actions (e.g. sensor test). You can also switch the device off manually after configuration using key **6**.

SOMNO*lab* 2 switches on at the time set for measuring to start and starts recording.

SOMNO*lab* 2 switches off automatically at the programmed time. After the measurement, your patient takes off the sensors and the SOMNO*lab* 2 basic device and stows all the parts in the carrying bag.

Start and end of measurement for inpatient measurement

Switch on SOMNO*lab* 2. SOMNO*lab* 2 starts as soon as recording has been started in the SOMNO*lab* PC software.

Start recording manually

It is possible to start recording manually. This function needs to be activated in the software under **Extras/Options**.

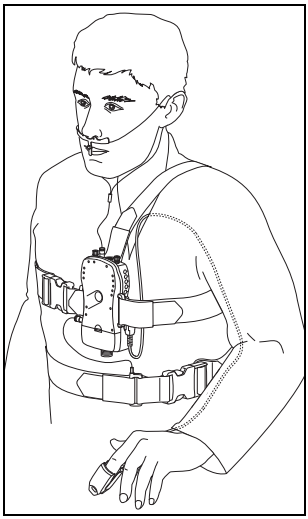
If the function has been activated, the device needs to be configured once. Only from this point can you start a recording manually independently of a configuration by keeping key **6** depressed for three seconds. The configuration of the previous measurement is always used in this case. Further

operation, e.g. setting the duration of measurement, can be found in the software.

5.4 Important notes for your patient

Observe the following points so that you and your patient are not irritated by faulty measurements.

- Never open the device.
- SOMNO*lab* 2 must be attached firmly, but comfortably, to the body so that body position is recorded correctly.
- The effort sensors must always be taut so that respiratory movements are recorded as well as possible.
- The cable of the pulsoximetry sensor should be secured on the patient's finger or hand with a plaster, for example. This stops the cable being a nuisance and prevents the sensor from slipping out of position.



- The patient should sleep with the window closed and alone, if appropriate, in order to prevent measuring results being falsified by unrelated noises.
- The sensors must be clean and dry. Contamination, such as secretions following sneezing, should be wiped off carefully.
- You can draw the cable of the pulsoximetry sensor through the sleeve of your patient's pajama top before attaching the sensor to his finger.
- The patient should avoid pulling the blankets or pillow over his or her head. This would significantly increase ambient temperature,

resulting in the respiratory flow snore sensor delivering faulty measurement data.

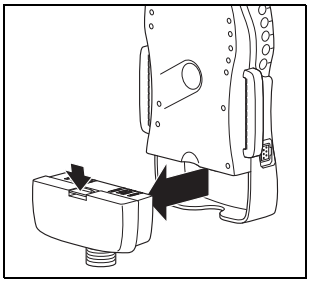
- The fingernail of the index finger to which the pulsoximetry sensor is attached may not be painted with colored nail varnish. A measurement will likewise give incorrect results if it is performed on fingers with false nails made of acrylic.
- If the pulsoximetry sensor is pinching, the patient can attach the sensor to a different finger.
- Check the position of sensors and electrodes before the measurement (note: electrodes cannot be used with the SOMNO*lab* 2 effort). Too high a transitional resistance between the electrodes and the skin, due to poorly affixed electrodes for example, delivers unsatisfactory recordings. Check the electrodes are secure and check their electrical properties. You can check the quality of electrode application by means of an impedance test (see "Perform a sensor test (not on the SOMNOlab 2 effort)" on Page 58).
- Replacing the battery does not cause the loss of any saved data, as these are archived on the memory card. Once 30 minutes have passed without a battery or a power supply, however, the device will have to be reconfigured.

- Let your patient know that he or she needs to be able to see microphone **20** on respiratory flow snore sensor **17** in the mirror after it has been put on.
- Tell your patient to check again that the belts are secure once he or she lies down.

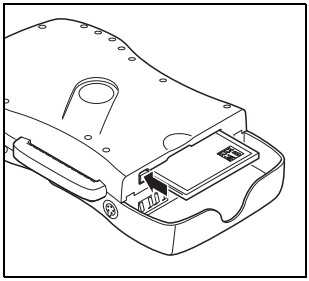
5.5 RemoveCompactFlash card

Proceed as follows to read out or change the CompactFlash card.

RemoveCompactFlash card



1. Remove the battery by pressing battery latch **7** and taking the battery out of the bracket.



2. Press the button on the left of the inserted CompactFlash card once briefly. The button now protrudes slightly.
3. Press the button again, this time until it engages again with a click and is flush with the housing. This pushes theCompactFlash card out of the device slightly and you can now remove it.

InsertCompactFlash card

1. Push in theCompactFlash card (with the contact holes facing the device and the labeling facing upwards) until it engages with a click and is flush with the housing.
2. Push the battery into SOMNO*lab* 2 until it engages with an audible click.

6. Handling the battery

SOMNO*lab* 2 has a high-capacity lithium ion battery. The charging electronics are in the power pack. These allow continuous capacity monitoring. If a defect is detected in the battery, (e.g. capacity is too low), there is a visual warning from the LEDs on the device.

Caution! If you remove the battery, you must insert a new or recharged battery within 30 minutes, otherwise SOMNO*lab* 2 will have to be reconfigured for any offline measurement which may be planned.

You can also remove the power pack from the SOMNO*lab* 2 and charge it using the charging/data transfer cable in combination with the USB/PC electrical isolation module, as well as the power supply unit.

If you have a second battery, you can return the device to your patient without delay and charge the empty battery later.

For how to remove/change the battery, see the section entitled "6.2 Service life" on Page 66.

Battery capacity is checked every time the device is configured and the PC software/firmware generates an information signal.

6.1 Charge battery

Precautions

- Ensure that your battery is fully recharged following a prolonged measurement.

- SOMNO*lab* 2 batteries can be recharged at any time. There is no memory effect. Even fully charging in several stages with or without interim partial discharge will not cause any harm.
- The battery of SOMNO*lab* 2 should not become fully discharged in normal daily use, so do not operate SOMNO*lab* 2 until it switches off automatically. Although discharging it completely will not directly reduce its capacity, the number of possible charging cycles drops dramatically. This will reduce service life if the battery is used frequently.
- To care for the SOMNO*lab* 2 battery, you should discharge the battery completely every 4-6 months and then recharge it. SOMNO*lab* 2 has an "intelligent" battery. The power pack includes electronics which are able, among other things, to determine capacity so as to calculate the running time displayed. To perform a full discharge, configure a 12-hour measurement without charging the battery beforehand.
- This battery will not tolerate deep discharge. This can be caused, for example, if the battery is stored for several months without being recharged from time to time.
- Cell oxidation continuously reduces battery capacity. This process is accelerated at elevated temperatures and a state of greater discharge.
- The natural discharge of a lithium ion battery as a result of internal chemical processes and the energy required by the protective circuit is approximately 3 % - 10 % a month.
- The battery can be operated and discharged at temperatures between +5 °C and +40 °C.
- Charging is possible only at battery temperatures between +5 °C and +35 °C.

- At temperatures of over 25 °C, the charging time for the battery increases.

Charging process

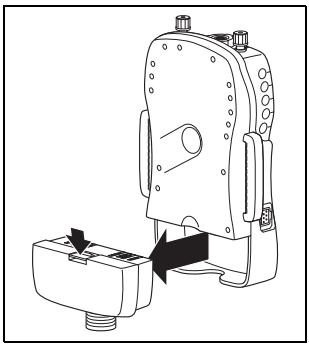
You can charge the battery in the device using the power supply unit **35** supplied, or, if you have two batteries, charge them externally. In the latter case, you can give the device to a new patient on a change of patients without wasting any time.

1. Plug connector **37** of power supply unit **35** into connection **43** on the USB/PC electrical isolation module **40**.
2. Plug one connector of charging/data transfer cable **38** into the corresponding connection **8** on the battery, the other connector into the corresponding connection **41** on the USB/PC electrical isolation module **40**.
3. Plug connector **37** of power supply unit **35** into a power supply socket. Yellow LED **5** next to the battery symbol on the battery comes on.
4. Charge the battery until the yellow LED on the battery goes out.

Save yourself work. Leave the power supply unit permanently plugged into a power supply socket and the USB cable connector plugged into your PC. This means the connector for SOMNO*lab* 2 is always handy on your desk.

6.2 Service life

- Li ion batteries have a service life of about 500 charging cycles. An incomplete discharge/ charge cycle also counts as a charge cycle.



- If the battery is **not charged**, service life is 1 year.
- Protect the battery from heat. If the battery is stored at temperatures of over +60 °C for a prolonged period (in direct sunlight in a car, for example), it will lose capacity permanently.
- Replace the battery once its service life is over. You can remove the battery by pressing latch **7** and taking the battery out of the bracket.
- Insert battery: push the battery into SOMNO*lab* 2 until it engages with an audible click.

6.3 Storage

- Batteries should be stored at 50 % charge and room temperature. Lithium ion batteries age significantly at full charge and a high storage temperature.

6.4 Battery disposal

Do not dispose of the battery in domestic waste. To dispose of the battery properly, contact an approved, certified electronics scrap dealer. You can obtain the address from your Environment Officer or your local authority.

7. Hygiene treatment

This product may contain disposable items.
Disposable items are intended to be used only once. So use these items only once and do **not** reprocess them. Reprocessing disposable items may impair the functionality and safety of the product and lead to unforeseeable reactions as a result of ageing, embrittlement, wear, thermal load, the effects of chemical processes, etc.

Note For cleaning and disinfecting, follow the recommendations of the Kommission für Krankenhaus, Hygiene und Infektionsprävention [Commission for Hospitals, Hygiene and the Prevention of Infection] of the Robert-Koch-Institut (RKI) and of the BfArM [Bundesinstitut für Arzneimittel und Medizinprodukte – Federal Institute for Pharmaceuticals and Medical Devices] regarding hygiene requirements when treating medical devices (Bundesgesundheitsblatt [Federal Health Gazette] 44/2001).

For hygiene treatment of the accessories, see the instructions for use in question.

7.1 Intervals

Part	When?		Clean		Disinfect		
	After every use	On changing patient	Cleanby hand	Washing machine	Disinfect by wiping	Disinfect by spraying	Disinfect by immersion
SOMNO*lab* 2/SOMNO*lab* 2 effort basic devices		•	•				
Pneumo-T-adapter	•		•				•
Pulsoximetry sensor (follow instructions for use)	•		•		•		
Respiratory flow snore sensor	•		•			•	
Respiratory flow oral sensor	•		•			•	
Abdomen sensor	•		•				
Press-stud electrodes, gold cup electrodes and electrode cables (see note enclosed in pack)	•		•		•		
Bags and belts		•	•	•			
Charging/data transfer cable		•	•		•		
R&K or AASM master cable	•		•				
ECG master cable	•		•				
ECG master cable extension	•		•				
Battery		•	•				
Respiratory flow nasal cannula	Disposable item						
Adhesive electrodes from the electrode set	Disposable item						
Tubes for the Pneumo-T-adapter	Disposable item						

7.2 Clean

Use mild detergent or a damp cloth

You can wipe down all the components of SOMNO*lab* 2 using a slightly damp cloth and a mild detergent.

If the Pneumo-T-adapter is very dirty, you can also immerse it in a mild soap solution.

Leave all the components to dry fully in air before using them again.

Caution! No liquid may get into SOMNO*lab* 2 or into the plug connections or sockets. The sensors may not be immersed in liquid. Before cleaning, it is essential to seal the pressure connections of the device using the stoppers!

Remove the power pack. Disconnect the charging/ data transfer cable from the battery before each cleaning operation and disconnect the power supply unit from the power supply socket.

In a washing machine

The carrying bag and the belts can be washed in a washing machine at 40 °C. Leave the bags and belts to dry in air.

Caution!

- Do not use a tumble dryer!
- Remove the abdomen sensor beforehand.

7.3 Disinfect

You may disinfect some parts by wiping or immersion when required, e.g. in the event of infectious diseases or unusual contamination (see "7.1 Intervals" on Page 69).

Follow the instructions for use for the disinfectant used. We recommend using suitable gloves (e.g. household or disposable gloves) when disinfecting.

- Disinfect by wiping with terralin® protect.

  To do this, take a disposable cloth and spray with the spray. Then wipe over the corresponding part.
- Spray-disinfect using MIKROZID® LIQUID spray.
- Disinfect by immersion using gigasept FF® (new).

7.4 Disposable items

For hygiene reasons, do not use disposable items which have been used; instead put the nasal cannula etc. in domestic waste. The relevant hygiene regulations should be observed in sleep laboratories/ clinical facilities.

7.5 Accessories

Follow the instructions enclosed with each accessory.

7.6 Non-medical devices

Follow the cleaning instructions in the instructions for use for the individual components enclosed with your delivery.

8. Function check

Perform the following measures before each use/ after any installation (note: electrodes and wireless data transmission cannot be used on the SOMNO*lab* 2 effort model).

- Ensure that all devices and sensors used are undamaged and fully functional. To this end, you can perform an online application check using the PC.

  To do this, put on the SOMNO*lab* 2 polygraphy system with all its sensors and electrodes and perform a measurement on yourself. You can assess the plausibility of the data on the PC.

- Check the function of the electrode cables in particular. Replace these after no more than 50 uses.

- Connect SOMNO*lab* 2 to the PC using the charging/data transfer cable or wirelessly. Ensure that the device is correctly connected to the PC using the appropriate charging/data transfer cables and the card reader unit for the CompactFlash card. Start the SOMNO*lab* PC software. Select the appropriate type of data transfer and start a measurement. Perform this test using the charging/data transfer cable, the wireless module and, if present, the network USB server.

- Configure the device using the card reader unit for CompactFlash cards. Perform a brief recording and read out the card again.

- Check communication between the components of SOMNO*lab* 2 and the PC system by triggering the sensor test and the impedance measurement and testing the function of the sensors. Observe the plausibility of the signals.

You can put SOMNO*lab* 2 on yourself to test the function of sensors or of the device.

- This function check is not a substitute for the checks on the device which are performed in the course of servicing.

9. Troubleshooting

9.1 SOMNO*lab* 2/SOMNO*lab* 2 effort basic devices

Note the scope of function for your SOMNO*lab* 2 when troubleshooting .

Fault	Cause of fault	Remedy
No signal in flow, snore, effort and/or pulsoximetry channel.	The respiratory flow snore sensor and/or the pulsoximetry sensor are not attached.	Put on the missing sensor.
	Plug connections are not properly connected.	Ensure the connections are firm.
	The sensors are dirty, damp or defective.	Clean the sensors and wipe them dry. Replace them if necessary.
A signal graph has a non-physiological curve.	Plug connections are not properly connected.	Ensure the connections are firm. Perform a sensor test before or during the measurement.
	The electrodes are dirty, damp or defective.	Clean the electrodes and wipe them dry. Replace them if necessary.
	The electrodes have got dirty or have slipped out of position during the measurement.	Repeat the measurement using clean electrodes and check that they are in the correct position.
	The sensor has got dirty or has slipped out of position during the measurement.	Repeat the measurement using clean sensors and check that they are in the correct position.
	EMC interference in the electrode cables.	Very rarely, certain frequencies of electromagnetic radiation from the environment can cause the amplitude of signals to be reduced. You can recognize this interference as fluctuations in amplitude by their non-physiological characteristic. These amplitude fluctuations do not influence the frequency or fundamental shape of the basic wave. Maintain the stated safety distances from other equipment (see "13.1 Safety distances" on page 90).

Fault	Cause of fault	Remedy
The ECG/other EXG channels are displaying a zero line.	The transitional resistances between the skin and the electrodes are too high.	Clean the skin and use new electrodes.
SOMNO*lab* 2 displaying no signals.	Plug connections are not properly connected.	Ensure the connections are firm.
	Channels not configured in display.	Configure the channels.
	Channels not configured in measuring mode.	Repeat the measurement with the correct configuration.
	Fault in the USB/PC electrical isolation module.	Disconnect all cables from the USB/PC electrical isolation module, then reconnect. **Tip:** If access to the USB/PC electrical isolation module is poor, disconnect the USB cable from the Transferbox 2, then restore the connection after a minimum of 3 s.
The electrophysiological signals are noisy.	The cables are receiving interference from the environment or are interfering with one another.	Put the electrode cables in different positions.
No connection can be made between the PC and SOMNO*lab* 2.	Interference in radio section (not on the SOMNO*lab* 2 effort).	All data are also stored internally in the device. You can read the data out the next day.
	Cable connection between device and PC is interrupted.	Check all cable connections.
LED for power supply not on.	Power supply unit not connected to the electricity supply.	Connect the device to the electricity supply.
The battery is not supplying any current.	Contact springs have no contact.	Put the battery in again.
	Battery has been charged more than 500 times, no longer reaching maximum capacity. Message in the software.	Replace the battery.
	Battery defective, e.g. as a result of a short-circuit or defective charging electronics.	Replace the battery.
Yellow LED on battery flashing.	Ambient temperature too high during charging (e.g. device lying on a windowsill in the sunshine).	Charge the battery at a lower ambient temperature.
Poor, noisy signals transmitted for ExG.	Filter configuration of the visualization filter not set to suit signal.	Adapt the low-pass and high-pass filters in the filter configuration (see online Help).

9.2 SOMNO*lab* software

Fault	Cause of fault	Remedy
Program cannot make a connection between the PC and SOMNO*lab* 2.	The radio link has been broken.	All data are also stored internally in the device. You can read the data out the next day.
	The charging/data transfer cable is not connected to the PC.	Connect the cable.
	Fault in the USB/PC electrical isolation module	Disconnect all cables from the USB/PC electrical isolation module, then reconnect. **Tip:** If access to the USB/PC electrical isolation module is poor, disconnect the USB cable from the Transferbox 2, then restore the connection after a minimum of 3 s.
	The corresponding diagnosis device is not activated.	Activate the device in the SOMNO*lab* PC software under **Extras/Options/ General** by putting a tick in the item **Supported devices** to activate this option.
The SOMNO*lab* PC software crashes.	Power failure of the electricity supply or interruption to the LAN connection during a measurement	Restart the PC and the SOMNO*lab* PC software. Resume the measurement.

10. Maintenance, servicing

SOMNO*lab* 2 must be serviced by the manufacturer or by a qualified specialist dealer every two years to guarantee its functional capability.

The following tasks must be performed.

- A function test takes place in SOMNO*lab* 2.
- The pressure sensor for xPAP pressure and flow measurement is tested and recalibrated if necessary. As soon as a pressure calibration becomes necessary, this automatically appears in the SOMNO*lab* PC software under **Events and remarks**.
- The electrophysiological amplifiers are checked for accuracy and may be recalibrated.
- The function and accuracy of all sensors and connectors are checked.
- Defective parts and contaminated tubes are replaced.

If SOMNO*lab* 2 is used daily, replace theCompactFlash card every 2 years. See also the section entitled "6. Handling the battery" on Page 64.

If you have any questions or problems, contact our hotline on telephone no.: +49 40 54702-101
e-mail: somnocheck.hotline@weinmann.de

11. Disposal

Do not dispose of the device with domestic waste. To dispose of the device properly, contact an approved, certified electronics scrap dealer. You can obtain the address from your Environment Officer or your local authority.

12. Scope of supply/replacement parts/accessories

1.	SOMNO*lab* 2 effort, polygraphy system	WM 95480
2.	SOMNO*lab* 2 PG, expanded polygraphy system	WM 95420
3.	SOMNO*lab* 2 PSG (R&K), polysomnography system	WM 95400
4.	SOMNO*lab* 2 PSG (AASM), polysomnography system	WM 95260
5.	SOMNO*lab* 2, complete package	WM 95050

S = scope of supply

R = replacement part

12.1 Basic devices

Order no.	Article	WM 95420	WM 95400	WM 95260	WM 95050	WM 95480
WM 95410	SOMNO*lab* 2 basic device	**S / R**	**S / R**	**S / R**	**S / R**	**-**
WM 95481	SOMNO*lab* 2 effort basic device	**-**	**-**	**-**	**S / R**	**S / R**
WM 95115	Power pack with capacity monitoring	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 95155	Loop abdomen sensor	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 94053	Attachment belt, 1.10 m long, yellow buckle	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 94054	Attachment belt, 1.5 m long, green buckle	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 94082	Abdominal belt, 1.5 m long, green buckle	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 94083	Abdominal belt, 1.10 m long, yellow buckle	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 95151	2x connecting strap with 40 mm closure	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 94055	Carrying bag	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 98500	SOMNO*lab* PC software	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 95090	Power supply unit	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 95116	Charging/data transfer cable	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 95091	USB/PC electrical isolation module	**S / R**	**S / R**	**S / R**	**S / R**	**S / R**
WM 96501	Set, electrodes	**S / R**	**S / R**	**S / R**	**S / R**	**-**
WM 96502	Set, removable cards	**S / R**	**S / R**	**S / R**	**S / R**	**-**
WM 95093	Removable card for "Application 1"	**-**	**-**	**-**	**-**	**S / R**
WM 95083	Pneumo-T-adapter incl. 5 tubes	**S / R**	**S / R**	**S / R**	**S / R**	**R**
WM 95235	R&K upgrade set, consisting of:	**-**	**S / R**	**-**	**R**	**-**
WM 95206	– R&K master cable		**R**		**R**	
WM 95207	– 3-pin ECG master cable		**R**		**R**	
WM 95421	– ECG master cable extension		**R**		**R**	
WM 95252	– master cable bracket		**R**		**R**	
WM 95233	– set of electrodes for SOMNO*lab* 2 polysomnography device		**R**		**R**	
WM 95097	– removable card for "Application 5", R&K		**R**		**R**	
WM 95237	– upgrade symbol for polysomnography device		**R**		**R**	

Order no.	Article	WM 95420	WM 95400	WM 95260	WM 95050	WM 95480
WM 95256	AASM upgrade set, consisting of:			S / R	R	
WM 95205	– AASM master cable			R	R	
WM 95207	– 3-pin ECG master cable			R	R	
	– ECG master cable extension			R	R	
WM 95252	– master cable bracket			R	R	
WM 95233	– set of electrodes for SOMNO*lab* 2 polysomnography device	-	-	R	R	-
WM 95097	– removable card for "Application 5", R&K			R	R	
WM 95237	– upgrade symbol for polysomnography device			R	R	
WM 95051	Plug of R&K or AASM master cable connection	R	R	R	S / R	S / R
WM 95238	Application sticker	R	R	R	S / R	-
WM 95239	France II application sticker	R	R	R	S / R	-
WM 96551	Set, SOMNO*lab* 2 PSG (electrodes (single use electrodes))	R	R	R	S / R	-

Weinmann offers a large range of EXG electrodes, which you can purchase individually or in sets as spare parts. Contact your Weinmann specialist supplier, or take a look at the price list.

12.2 Pulsoximetry sensors

Order no.	Article	WM 95420	WM 95400	WM 95260	WM 95050	WM 95480
WM 18040	Softtip sensor SpO_2, size S	R	R	R	S / R	R
WM 18030	Softtip sensor SpO_2, size M	R	R	R	S / R	R
WM 18035	Softtip sensor SpO_2, size L	S / R	S / R	S / R	R	S / R
WM 95105	Pulsoximeter, Minimed clip sensor 90 °, 140 cm cable	R	R	R	S/R	R

12.3 Flow/snore measurement – therapy check

Order no.	Article	WM 95420	WM 95400	WM 95260	WM 95050	WM 95480
WM 94010	Respiratory flow snore sensor for adults, large	**R**	**R**	**R**	**S / R**	**R**
WM 95082	Respiratory flow oral sensor	**R**	**R**	**R**	**S / R**	**R**
WM 94043	Respiratory flow nasal cannula	**R**	**R**	**R**	**S / R**	**R**
WM 94044	Respiratory flow nasal cannula set	**S / R**	**S / R**	**R**	**R**	**S / R**
WM 94045	Respiratory flow nasal cannula, 50-pack	**R**	**R**	**R**	**S / R**	**R**
WM 95222	Set of 100 diagnostic nasal cannulas 330 mm and 1 adapter	**R**	**R**	**R**	**S / R**	**R**
WM 96503	Set of 20 tubes for Pneumo-T-adapter	**R**	**R**	**R**	**S / R**	**R**
WM 95263	Flexible tube adapter	**R**	**R**	**R**	**S / R**	**R**
WM 94042	Stopper for pressure measurement connection	**R**	**R**	**R**	**R**	**R**

12.4 Data transfer

Order no.	Article	WM 95420	WM 95400	WM 95260	WM 95050	WM 95480
WM 95085	TCP/IP network USB server	**R**	**R**	**R**	**S / R**	**R**
WM 95076	USB cable, 2 m	**S / R**	**S / R**	**S / R**	**R**	**S / R**
WM 95087	Card reader unit for CompactFlash cards	**R**	**R**	**R**	**S / R**	**R**
WM 95202	CompactFlash card	**S / R**	**S / R**	**S / R**	**R**	**S / R**

12.5 Power supply options

Order no.	Article	WM 95420	WM 95400	WM 95260	WM 95050	WM 95480
WM 95089	Primary adapter, GB	**R**	**R**	**R**	**S / R**	**R**
WM 95092	Primary adapter USA/Japan	**R**	**R**	**R**	**S / R**	**R**
WM 95098	Primary adapter AU, NZ	**R**	**R**	**R**	**S / R**	**R**

12.6 Accessories

Order no.	Article	WM 95420	WM 95400	WM 95260	WM 95050	WM 95480
WM 95300	Transferbox 2	**R**	**R**	**R**	**R**	**-**
WM 95358	SOMNO*butler* 2 stationary	**R**	**R**	**R**	**R**	**R**
WM 95359	SOMNO*butler* 2 mobile	**R**	**R**	**R**	**R**	**R**

13. Technical data

SOMNO*lab* 2/SOMNO*lab* 2 effort basic devices

Product class to 93/42/EEC	IIa
Dimensions (W x H x D)	80 x 150 x 34 mm
Weight (device excl. sensors) – SOMNO*lab* 2 – SOMNO*lab* 2 effort	 approx. 300 g approx. 220 g
Temperature range: – operation – storage	 +5 °C to +40 °C* –10 °C to +60 °C
Power supply, basic device	3.7 V DC
Power supply, battery	7.5 V DC
Mean power consumption	approx. 340 mW
Battery operating time: – wireless online – mobile	 approx. 10 hours approx. 20 hours
Max. recording period for one measurement	12 hours
Electrical rating, power supply unit	Input: 100-240 V, 50-60 Hz, 400 mA Output: 7.5 V DC
Classification to EN 60601-1 – Type of protection against electric shock – Degree of protection against electric shock	 Protection class II Type BF

Electromagnetic compatibility (EMC) to EN 60601-1-2 – Radio interference suppression – Radio interference immunity	(Test parameters and limit values can be obtained from the manufacturer on request) EN 55011 EN 61000-4 Parts 2 to 6, Part 11
Type of protection against ingress of water	IPX0
Relative humidity for operation and storage	25 to 95 %, no condensation
Air pressure for operation and storage	700 to 1060 hPa
Storage medium	CompactFlash card, max. 2 GB
Data transfer online	– Wireless via radio signals at 2.4 GHz (not on the SOMNO*lab* 2 effort) – USB 1.1 or higher (electrically isolated)
Readout of saved data	USB 1.1 or higher Remove CompactFlash card, read in via CompactFlash card card reader unit

* Observe the temperature range of the respiratory flow snore sensor (see Page 28)

Radio module (not on the SOMNO*lab* 2 effort)

Carrier frequency band	2400 MHz to 2483.5 MHz
Type and frequency response of modulation	GFSK, 1 Mbps 0.5 BT Gaussian
Frequency hopping	1600 hops/s 1 MHz channel spacing
Skip frequency	2400 MHz to 2483.5 MHz F = 2402 + k MHz k = 0 to 78
Transmission power	Typical: 0 dBm (Class 2)
Receiving signal range	Typical: 80 dBm to -15 dBm
Receiver DC link frequency	1.5 MHz heterodyne down-converter
Protective area	2 MHz < F < 3.5 MHz for USA, Japan and Europe (except Spain and France)

Battery

Type of battery	Li ion
Voltage	3.6 V
Capacity	2.2 Ah
Overvoltage	4.35 V
Max. charge current	1 A
Normal discharge current	<1 A
Charge cycles	500
Charging time with device switched off	Approx. 3 hours. at 25 °C with battery discharged

Position sensor

Position sensor	Sensor integrated in device
Value range	Right-hand side, left-hand side, front, back, standing
Accuracy of position	Approx. 45° ±15°

CPAP/BiPAP/SmartPAP pressure

Measuring range	0 hPa to 40 hPa
Precision	±1 hPa

Respiratory flow

Respiratory flow snore sensor	3 thermistors as summation signal, no measuring function at ambient temperatures between 33 °C to 38 °C
Respiratory flow nasal cannula	Pressure fluctuations on inspiration/exhalation
Respiratory flow oral sensor	One thermistor, no measuring function at ambient temperatures between 33 °C to 38 °C

Differential flow pressure

Pneumo-T-adapter	Tapered connector to ISO 22 standard
Sensor	Differential pressure: pressure fluctuations on inspiration/exhalation

Effort sensors (thorax, abdomen)

Thorax sensor	Sensor integrated in device
Method	Piezoelectric measurement

Snoring

Respiratory flow snore sensor	Integrated microphone
Respiratory flow nasal cannula	Pressure sensor
Pneumo-T-adapter	Pressure sensor
Method	Log. mean value of sound pressure signal (microphone) or of pressure fluctuations (pressure sensor)

Electrodes

Contact-proof connectors to DIN 42802	1.5 mm

CE 0197

The right to make design modifications is reserved.

Pulsoximetry sensor				
Parameter	**Value range**		**Unit**	**Precision/comment**
	Min.	**Max.**		
Sensor: wavelengths	660	905	nm	
Sensor: heat output	0	20	mW	Maximum rise in temperature by 2 °C at application location
Signal quality	0	100	%	A signal quality ≥ 90 % is good - below that, SpO_2 values and pulse frequency may be unreliable.
SpO2 measurement				
SpO_2 measuring range:	45	100	%	70 % ≤ SpO_2 ≤ 100 %: better than 2 % precision SpO_2 < 70 % not validated
Measuring dynamics First reaction after: Final value reached after:		2 8	s s	Measured at desaturation/resaturation between 96 % and 84 % SpO_2 under favorable measuring conditions. The values may be extended in the event of poor pulse strength or movement artifacts.
First display after application	3	6	s	Measured at default setting. The poorer the measuring conditions, the more unreliable the first value displayed.
Pulse frequency measurement				
Pulse frequency measuring range:	30	250	bpm	1 bpm to 2 % of displayed value
Measuring dynamics First reaction after: Final value after another:	1 1	7 6	s s	Maximum values measured in the case of sudden change from 40 to 200 bpm and vice versa. The times for reaction and final value depend on the difference (deviation) between beats.
First display after application	5	8	s	Measured at default setting. The poorer the measuring conditions, the more unreliable the first value displayed.

Electrophysiological signals in the basic device (not on the SOMNO*lab* 2 effort)				
EXG channels	**ECG**	**EEG**	**EMG**	**EOG**
Dynamic range (physical value range)	± 5 mV	±500 µV	±250 µV	±500 µV
Resolution	12 bits	12 bits	12 bits	12 bits
Amplitude precision	± 3 %	± 3 %	± 3 %	± 3 %
Frequency range precision	± 15 %	± 15 %	± 15 %	± 15 %
Frequency range in the hardware	0.05 Hz	0.05 Hz	0.05 Hz	0.05 Hz
High-pass filter in device software	0.02 Hz	0.5 Hz	2.7 Hz	0.5 Hz
Scanning rate	256 Hz	256 Hz	256 Hz	256 Hz
The following can be configured	ECG, EEG, EMG, EOG			
Specification	as for ECG, EEG, EMG, EOG			
Input impedance	approx. 40 MΩ			

Electrophysiological signals in the basic device on R&K or AASM master cable and ECG master cable (not on the SOMNO*lab* 2 effort)			
EXG channels	**EEG**	**EOG**	**ECG**
Dynamic range (physical value range)	±500 µV	±500 µV	±500 µV
Resolution	12 bits	12 bits	12 bits
Amplitude precision	± 3 %	± 3 %	± 3 %
Frequency range precision	± 15 %	± 15 %	± 15 %
Frequency range in the hardware	0.05 Hz	0.05 Hz	0.05 Hz
High-pass filter in device software	0.5 Hz	0.5 Hz	0.02 Hz
Scanning rate	256 Hz	256 Hz	256 Hz
Input impedance	approx. 40 MΩ		
Note	These channels are permanently configured		

Signals and scanning rates				Recommended filters and scales for visualization				
No.	Name	Source	Scanning rate in Hz	High-pass filter	Low-pass filter	Lock-out	Scale	
							from	to
1	Flow I	Nasal cannula/ Pneumo-T-adapter	32	None	5 Hz	None	-128	128
2	Flow II	Flow/snore sensor	32	0.1 Hz	1 Hz	None	-128	128
3	Effort, thorax	Thorax belt - piezo	32	0.05 Hz	0.8 Hz	None	-128	128
4	Effort, abdomen	Abdominal belt - piezo	32	0.05 Hz	0.8 Hz	None	-128	128
5	Snoring	Nasal cannula/flow/ snore sensor	16	None	None	None	0	256
6	Flattening	Pneumo-T-adapter	8	None	None	None	0	100
7	Saturation	Finger sensor	16	None	None	None	70	100
8	Pulse PF	Finger sensor	16	None	None	None	50	120
9	Pulse HF(1)	ECG	16	None	None	None	50	120
10	Pressure	Pneumo-T-adapter	32	None	None	None	4	18
11	Leakage	Pneumo-T-adapter	8	None	None	None	0	100
12	Position	Position sensor, integrated	16	None	None	None		
13	Respiratory frequency	Nasal cannula/ Pneumo-T-adapter	8	None	None	None	0	20
14	Quality	Finger sensor	10	None	None	None	None	None
15	Plethysmogram	Finger sensor	50	None	None	None	None	None
16	EMG(1)	Electrodes	256	10 Hz	70 Hz	50 Hz	-100	100
17	EKG(1)	Electrodes	256	0.1 Hz	70 Hz	50 Hz	-1500	2500
18	EEG(1)	Electrodes	256	0.5 Hz	20 Hz	None	-80	80
19	EOG(1)	Electrodes	256	0.5 Hz	30 Hz	None	-120	120

(1) not on the SOMNO*lab* 2 effort

13.1 Safety distances

Electrical medical devices require special precautionary measures as regards electromagnetic compatibility (EMC). They must be installed and put into operation in accordance with the EMC instructions contained in the accompanying documentation.

Recommended safety distances between portable and mobile HF telecommunication devices (e.g. cellphones) and SOMNO*lab* 2			
Nominal power of HF device in W	**Safety distance depending on transmission frequency in m**		
	150 KHz - 80 MHz	**80 MHz – 800 MHz**	**800 MHz – 2.5 GHz**
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.11	1.11	2.21
100	3.50	3.50	7.00

Further technical details can be obtained from the manufacturer, Weinmann, on request.

13.2 Technical data for non-medical components

Please observe the instructions for use for the individual components enclosed with your delivery.

14. Warranty

Weinmann gives the customer a limited manufacturer warranty on new genuine Weinmann products and any replacement part fitted by Weinmann in accordance with the warranty conditions applicable to the product in question and in accordance with the warranty periods from date of purchase as listed below. The warranty conditions can be downloaded from www.weinmann.de on the Internet. We can also send you the warranty conditions on request.

In the event of a claim under warranty, contact your specialist dealer.

Product	Warranty period
Weinmann devices including accessories (except masks) for sleep diagnosis, sleep therapy, home ventilation, oxygen medicine and emergency medicine	2 years
Masks including accessories, rechargeable battery, batteries (unless there is information to the contrary in the technical documentation), sensors, tube systems	6 months
Disposable products	None

15. Declaration of conformity

Weinmann Geräte für Medizin GmbH + Co. KG hereby declares that the product complies with the relevant provisions of directive 93/42/EEC pertaining to medical devices.

The complete text of the declaration of conformity can be found at: www.weinmann.de

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